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

FORM 10-Q

☒ **QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2008.

OR

☐ **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT**
For the transition period from _____ to _____

Commission File Number: 000-50614

ORAGENICS, INC.

(Exact name of small business issuer as specified in its charter)

FLORIDA	**59-3410522**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

13700 Progress Boulevard
Alachua, Florida 32615
(Address of principal executive offices)

(386) 418-4018
(Issuer's telephone number)

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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 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," "non-accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	**Accelerated filer**	☐
Non-accelerated filer	☐	**Smaller reporting company**	☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date:

As of November 4th, 2008, there were 38,318,478 shares of Common Stock, $.001 par value, outstanding.

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Oragenics, Inc.

Balance Sheets

	September 30, 2008 (Unaudited)	December 31, 2007
Assets		
Current assets:		
Cash and cash equivalents	$ 2,699,760	$ 475,508
Prepaid expenses and other current assets	184,086	116,520
Total current assets	2,883,846	592,028
Property and equipment, net	382,802	559,349
Total assets	$ 3,266,648	$ 1,151,377
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 377,829	$ 244,994
Current portion of note payable	52,963	–
Deferred compensation	42,750	86,500
Total current liabilities	473,542	331,494
Stockholders' equity:		
Preferred stock, no par value; 20,000,000 shares authorized; none issued and outstanding at September 30, 2008 and December 31, 2007	–	–
Common stock, $0.001 par value; 100,000,000 shares authorized; 38,318,478 and 28,002,443 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	38,318	28,002
Additional paid-in-capital	19,750,446	14,762,674
Accumulated deficit	(16,995,658)	(13,970,793)
Total stockholders' equity	2,793,106	819,883
Total liabilities and stockholders' equity	$ 3,266,648	$ 1,151,377

See accompanying notes.

Oragenics, Inc.

Statements of Operations
(Unaudited)

	Three months ended September 30		Nine months ended September 30	
	2008	2007	2008	2007
Revenue	$ 100,000	$ 46,584	$ 225,000	$ 106,345
Operating expenses:				
Research and development	503,685	337,021	1,474,725	1,109,297
General and administration	749,515	205,300	1,816,123	644,725
Total operating expenses	(1,253,200)	542,321	3,290,848	1,754,022
Loss from operations	(1,153,200)	(495,737)	(3,065,848)	(1,647,677)
Other income:				
Interest income	15,083	8,403	29,413	22,797
Gain on sale of property and equipment	–	–	4,860	–
Sales tax refund	–	–	6,710	–
Total other income	15,083	8,403	40,983	22,797
Net loss	$ (1,138,117)	$ (487,334)	$ (3,024,865)	$ (1,624,880)
Basic and diluted net loss per share	$ (0.03)	$ (0.02)	$ (0.09)	$ (0.07)
Shares used to compute basic and diluted net loss per share	38,317,573	25,976,356	33,975,257	24,111,436

See accompanying notes.

Oragenics, Inc.

Statements of Cash Flows
(Unaudited)

	Nine months ended September 30	
	2008	**2007**
Operating activities		
Net loss	$ (3,024,865)	$ (1,624,880)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	190,565	206,528
Gain on sale of property and equipment	(4,860)	–
Stock-based compensation expense resulting from fair value based method	486,088	134,606
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(67,566)	(97,013)
Accounts payable and accrued expenses	132,835	(34,473)
Deferred compensation	(43,750)	(45,500)
Net cash used in operating activities	(2,331,553)	(1,460,732)
Investing activities		
Purchases of property and equipment	(51,408)	(9,861)
Proceeds from sale of property and equipment	42,250	–
Net cash used in investing activities	(9,158)	(9,861)
Financing activities		
Net proceeds from note payable	52,963	–
Net proceeds from issuance of common stock	4,512,000	1,698,990
Net cash provided by financing activities	4,564,963	1,698,990
Net increase in cash and cash equivalents	2,224,252	228,397
Cash and cash equivalents at beginning of period	475,508	707,278
Cash and cash equivalents at end of period	$ 2,699,760	$ 935,675

See accompanying notes.

Oragenics, Inc.

Notes to Financial Statements
(Unaudited)

1. Organization and Significant Accounting Policies

Oragenics, Inc. (d/b/a ONI BioPharma, Inc., formerly known as Oragen, Inc.) (the "Company" or "ONI") was incorporated in November 1996; however, operating activity did not commence until 1999. The Company is dedicated to developing technologies associated with oral health, broad spectrum antibiotics and general health benefits.

Basis of Presentation

The accompanying unaudited condensed financial statements as of September 30, 2008 and December 31, 2007 and for the three and nine months ended September 30, 2008 and 2007 have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the accompanying financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the financial condition, results of operations and cash flows for the periods presented. The results of operations for the interim period September 30, 2008 are not necessarily indicative of the results that may be expected for the year ended December 31, 2008 or any future period.

These financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2007, which are included in our Annual Report on Form 10-KSB filed with the Securities and Exchange Commission on March 18, 2008. In that report the Company disclosed that it expects to incur substantial expenditures to further develop each of its technologies and that it believes its working capital will be insufficient to meet the business objectives as presently structured and that without sufficient capital to fund its operations, the Company will be unable to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty. However, the Company currently believes that it will have sufficient resources to commercialize selective products and that it will obtain funding to further develop and commercialize other products.

2. Net Loss Per Share

Net loss per share is computed using the weighted average number of shares of common stock outstanding. Common equivalent shares from stock options and warrants are excluded as their effect is anti-dilutive.

3. Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rate is recognized in operations in the period that includes the enactment date. Deferred tax assets are reduced to estimated amounts expected to be realized by the use of a valuation allowance.

In September 2006, the FASB issued FASB Interpretation No. 48, "*Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statements No. 109*" (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing a two-step method of first evaluating whether a tax position has met a more likely than not recognition threshold and second, measuring that tax position to determine the amount of benefit to be recognized in the financial statements. FIN 48 provides guidance on the presentation of such positions within a classified statement of financial position as well as on derecognition, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 was adopted by the Company effective January 1, 2007. As a result of the implementation of FIN 48, the Company did not recognize a change in its tax liabilities or assets as of September 30, 2008.

4. Fair Value of Financial Instruments

SFAS No. 157, *Fair Value Measurements* ("SFAS 157"), defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 establishes a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value as follows:

Level 1. Observable inputs such as quoted prices in active markets;

Level 2. Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3. Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The Company does not have any assets or liabilities measured at fair value on a recurring basis at September 30, 2008. The Company did not have any fair value adjustments for assets and liabilities measured at fair value on a nonrecurring basis during the nine months ended September 30, 2008.

5. Stock Options Issued During 3rd Quarter, 2008

During the quarter, the Company issued 320,000 stock options of which 60,000 vested immediately. The remaining options that have yet to vest will vest subject to the price of the stock reaching certain levels. The stock options were granted (1) to existing employees to supplement options that were previously granted that had exercise prices far out-of-the-money, and (2) to executive employees who recently joined the Company or will join the Company in the coming months. This increase in the number of options granted was partially offset by the number of stock options that have been forfeited. Since the beginning of the 3rd Quarter, 2008, through the date of this filing, 665,000 options that were previously granted have been forfeited. From January, 1, 2008 to the date of this filing, 905,000 stock options have been forfeited. Stock option compensation expense is a non-cash expense and is included in research and development and general and administrative expenses in the accompanying statements of operations.

6. Outstanding Warrants and Stock Options

As of the date of this filing there are approximately 5,855,278 warrants outstanding and there are approximately 3,945,000 stock options have been granted that have not been forfeited. The total number of outstanding warrants and unexercised stock options is 9,800,278. If all warrants and stock options were exercised, the total number of outstanding shares would be approximately 48,118,756.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following information should be read in conjunction with the Financial Statements, including the notes thereto, included elsewhere in this Form 10-Q. This discussion contains certain forward-looking statements that involve risks and uncertainties. Our actual results and the timing of certain events could differ materially from those discussed in these forward-looking statements as a result of certain factors, including, but not limited to, those set forth herein and elsewhere in this Form 10-Q.

Oragenics, Inc. d/b/a ONI BioPharma, Inc, (the "Company" or "ONI") has changed its strategy as it has the name under which it does business. ONI is no longer strictly a research and development company, but, as management expects, is now securely on the road towards the commercialization of some of its products. ONI is also moving forward with the clinical testing of other products to achieve registration in as timely a manner as possible. These opportunities have derived from our focus on creating novel technologies that apply to individual products as well as platforms from which numerous products can be developed.

Third Quarter Highlights & Recent Events

During the quarter and up to the date of this filing, the following significant events occurred:

- **Successful Synthesis of Lantibiotic using DPOLT^{tm}.** We announced the successful synthesis of an antibiotic using its proprietary DPOLT^{tm} technology. The molecule belongs to a class of antibiotics called Lantibiotics that were first discovered over 80 years ago. Although there are now over 50 different Lantibiotics known, this is the first report of a cost-effective method for making one in sufficient amounts and with sufficient purity to enable comprehensive testing and commercial viability. As a first step in further development, the Company has retained Almac Sciences, a leading contract manufacturer and a division of the Almac Group, to refine and scale-up GMP production of the synthetic MU1140^{tm} analogue to achieve sufficient quantities for it to be fully tested for regulatory approval. It is estimated that the regulatory process will take three years before this drug could become available. Other synthetic Lantibiotics will follow as they are developed and tested.

- **Marketing of ProBiora3^{tm} and EvoraPlus^{tm}.** We announced the launch of our marketing program for ProBiora3, our oral probiotic technology, which will initially include the introduction of EvoraPlus^{tm} into the marketplace. EvoraPlus^{tm} is the first of several products to be launched under the Evora^{tm} brand, which is our house brand. We anticipate the next Evora product that we will launch will be EvoraPet^{tm}. In our estimation, the initial response to ProBiora3^{tm} and EvoraPlus^{tm} has been exceptional. We have had several meetings with some of the largest retailers in the US who have expressed a strong interest in our products. We have received orders for both ProBiora3^{tm} and EvoraPlus^{tm} and expect to begin shipping in the fourth quarter of this year. For further information, please visit www.probiora3.com and www.evoraplus.com.

- **Diagnostics.** We recently entered into a Collaboration Agreement with a major, global diagnostics company regarding our gene targets for various stages of colorectal cancer that we discovered using the PCMAT^{tm} platform. We have also initiated a new internal program for both the PIVIAT^{tm} and PCMAT^{tm} platforms. Under this initiative whereby we will augment our development work by including the validation of gene targets we have discovered through the use of the platforms. We anticipate that this will in turn make our gene targets more valuable and decrease time to market for any test that utilizes them.

- **Formation of Mexican Subsidiary.** We initiated the formation of a Mexican Subsidiary. We anticipate that this Subsidiary will provide us with several advantages including reduced cost for clinical trials and access to the Latin American markets. We will begin marketing EvoraPlus^{tm} in Mexico as soon as regulatory approval is achieved. We will also initiate further clinical trials for our SMaRT^{tm} Replacement Therapy technology which provides a one-time application for life-time prevention of dental caries (tooth decay). We have also begun the process of forming a collaboration with the Instituto de Biolotecnología, Universidad Nacional Autónoma de México ("IBUNAM"), the premier biotechnology institute in Mexico generally recognized as having the best and brightest scientists in Mexico. We expect to work with IBUNAM on several projects including projects to discover novel gene targets using our PIVIAT^{tm} and PCMAT^{tm} platforms.

Since ONI's inception, the Company has funded a significant portion of its operations from the public and private sales of its securities. There have been no significant revenues from operations during the last two years. All of our revenues have been from sponsored research agreements and various governmental grants. At this time we have not generated revenues from sales of products. Currently, we anticipate purchase orders and/or revenues from the sale of EvoraPlus^{tm}, our oral probiotic, as early as the 4th quarter of the current calendar year.

Management believes that we are now positioned over the next several months to generate revenues from a number of technologies. Furthermore, with respect to products that are not ready for immediate commercialization, we are taking what we regard to be concrete steps in completing the research and development of pending products and platforms. Consequently, our proofs of concept are essentially complete, and we are taking the steps necessary to bring our product portfolio to market, with the expectation, but not assurance that our products, where necessary, will be approved for marketing.

Business Objectives and Milestones

We have a number of products and platforms. For ease in understanding, we have broken these products and platforms down into four distinct Divisions:

(1) Consumer Products, which consists of ProBiora3^{tm}, the Evora^{tm} product line and LPT3-04^{tm};

(2) Diagnostics, which consists of the PIVIAT^{tm} and PCMAT^{tm} platforms;

(3) Antibiotics, which consists of the DPOLT^{tm} lantibiotic synthesis platform; and

(4) Replacement Therapy, which consists of our SMaRT^{tm} Replacement Therapy technology.

Consumer Products

The specific goal for our consumer products is to rapidly and effectively commercialize ProBiora3^{tm} and LPT3-04^{tm}.

ProBiora3^{tm} (Probiotics)

ProBiora3^{tm} contains three naturally occurring, live microorganisms that helps maintain dental and oral health when administered to the host in adequate amounts. The use of yogurt containing live *Lactobacillus* cultures is an example of a probiotic application. We will market ProBiora3^{tm} under self-proclaimed GRAS ("Generally Recognized As Safe") status, which will expedite our marketing efforts because it relieves us of the need for extensive regulatory oversight. Two sets of subjects completed our ProBiora3^{tm} human study in 2006, and we believe the results confirmed that the product is safe for human use and demonstrated a substantial effect of Probiora3 in reducing the levels of specific bacteria in the mouths of young, healthy adult subjects.

ONI has developed a bifurcated strategy where we will establish two separate brands; (1) where the actual technology, ProBiora3^{tm}, will be branded as an active ingredient for licensing and private labeling, and (2) where we will market products under the brand name Evora^{tm}, our house brand. Evora^{tm} products will contain different ratios, or blends, of the three natural strains contained in ProBiora3^{tm} and potentially different delivery mechanisms such that each product will be tailored to the needs of specific markets. The Evora^{tm} products currently in production or the product pipeline are:

- **EvoraPlus^{tm}**, a product with equal weight of all three strains that is optimally designed for the general consumer market.
- **EvoraPet^{tm}**, a product that has a mixture which focuses exclusively on gum disease, a problem endemic with cats and dogs.
- **EvoraKids^{tm}**, a product that has a greater concentration of strains designed to reduce dental caries, which is more of an issue for children.

Other Evora[tm] products with different formulations and delivery systems are also in planning. EvoraPlus[tm] will be the first product to market with EvoraPet[tm] expected to follow shortly thereafter. EvoraPlus[tm] will be a probiotic mint packaged in a 60 unit box with four 15 dose blister packs. The intended usage is to take one mint twice a day after brushing. As such, one box is designed to include a one-month's supply of EvoraPlus[tm]. ONI has completely outsourced the manufacturing and fulfillment process to a large, GMP certified manufacturer with the ability to scale production to meet our expected needs. The product is currently in production with anticipated completion in late October. It is anticipated that manufacturing costs will fall as production is scaled.

We believe ONI has made significant progress regarding the launch EvoraPlus[tm]. ONI has three primary channels in which it will market EvoraPlus[tm]; (1) Mass Retail, (2) Direct to Consumer ("DTC"), and (3) Dental Professionals. Regarding the Mass Retail channel, ONI has retained an experienced team of brokers to market the product to the largest retailers in the United States. Several initial meetings with several major retailers have already taken place. The response has been positive and management expects several orders beginning in the fourth quarter, 2008. ONI also plans on marketing through one or more television shopping networks by the end of the year. In the DTC channel, a one-minute spot television ad is currently in production and will run in key markets once product manufacturing has been completed. ONI has also developed an Internet strategy to market the product directly through our www.evoraplus.com website, which is expected to go live in the fourth quarter of 2008. Lastly, we have made significant progress in the Dental Professionals channel as well. The Company recently had a meeting with a large dental health company provides products and services to over 600 dental offices. Although discussions are at an early stage, they have expressed a strong interest in marketing the product to their clients and distributing it to independent dental offices. Lastly, we plan on aggressively marketing our products in Mexico and Latin America through our Mexican Subsidiary, which the Company is currently in the process of forming. We anticipate that we will begin selling and distributing EvoraPlus[tm] in Mexico in the first half of 2009.

Despite our efforts to commercialize ProBiora3[tm], there can be no assurances that we will meet our timeline for commercialization or that the product will meet the sales projections we have anticipated.

LPT3-04[tm]

LPT3-04[tm] is a small molecule weight management agent for which we filed a U.S. patent application on April 5, 2006 to protect our intellectual property rights to the agent and its analogs. As a natural substance, LPT3-04[tm] is orally available, and we believe it has an excellent safety and tolerability profile. As with ProBiora3[tm], LPT3-04[tm] would fall under the self-proclaimed GRAS status and we will be able to market products containing the technology without the burden of substantial regulatory oversight in most, if not all, of the markets in which we plan on introducing products.

Our strategy for our LPT3-04[tm] is similar to that of our oral probiotic in that we plan on developing a bifurcated strategy where we market the technology as an active ingredient for licensing or private labeling and we develop a house brand to market to consumers directly and through mass retail. We plan on developing several products under the house brand that will vary by formulation and delivery mechanism. We will also develop a product for the Pet Market since obesity is a problem that is present in the animal markets as well. Design work for the house brand is in progress and we anticipate having it completed by year's end. We may also market directly to Medical Professionals and Veterinary Offices.

We are currently in the process of developing an adequate delivery system for LPT3-04[tm]. We anticipate that this process will be complete by the end of the first quarter, 2009. Once this has been accomplished, we plan on initiating subsequent and more comprehensive human trials. These trials are currently expected to begin in early 2009. Our Mexican Subsidiary will play a crucial role in penetrating the Mexican and Latin American markets for our weight loss product. We anticipate that we will initiate marketing in Mexico and Latin America shortly after we launch in the US. We may also look to our Mexican Subsidiary for conducting clinical trials for the products.

Diagnostics

The goal of our Diagnostics unit is to utilize the PIVIAT[tm] and PCMAT[tm] platforms to identify and secure intellectual property rights to gene targets associated with the natural onset and progression of infections, cancers and other diseases in humans, animals, and agricultural products. We believe these platforms provide a number of profitable business models from which to realize value.

PIVIAT[tm] and PCMAT[tm]

Proteomics-based *In Vivo* Induced Antigen Technology (PIVIAT[tm]) is a platform technology that enables rapid identification of novel targets for use in the diagnosis and treatment of human infectious diseases. The method is faster, more cost effective, and more sensitive than other methods currently in use to identify such targets. As an example, a recent tuberculosis project has yielded 44 novel targets for *Mycobacterium tuberculosis* that are currently being analyzed for their use in vaccine and diagnostic strategies.

We are currently in discussions with various collaborators to look at specific diagnostic markers and to develop vaccines utilizing our PIVIAT[tm] gene targets.

Proteomics-based Change Mediated Antigen Technology (PCMAT[tm]) is a platform technology that was derived from and greatly extends the potential applicability of PIVIAT[tm]. This technology rapidly identifies proteins (and their genes) that are expressed when a cell undergoes any sort of change. PCMAT[tm] has been used to identify proteins of plants that are expressed when it becomes infected. Such genes are excellent targets for manipulation to increase the resistance of the plant to infection. It has also been used to identify novel proteins of human bowel cells that are expressed when the cell undergoes transformation to a cancerous cell. Such proteins are excellent targets for new diagnostics and therapeutic strategies. PCMAT[tm] has the potential to study an extraordinary range of medical and agricultural applications.

The first major commercial effort that we have undertaken utilizing the PCMAT[tm] platform has been to extract genetic targets from tissue samples containing colorectal cancer. Colorectal cancer affects millions of people worldwide. The current "Gold Standard" in the detection of colorectal cancer is the use of a colonoscopy. Due to the invasive nature and cost of colonoscopies, patient compliance is low. As such, many cases of bowel cancer go undetected until the cancer has reached an advanced stage. Using the PCMAT[tm] diagnostic platform, we have discovered what we believe to be unique genetic markers that appear during the earliest stages of colorectal cancer. As announced, we recently entered into a Collaboration Agreement with a major, global diagnostics company regarding our gene targets for various stages of colorectal cancer that we discovered using the PCMAT[tm] platform. Although we are highly optimistic about this Collaboration Agreement, there can be no assurances that this Agreement will result in a diagnostic test that will be marketed to appropriate health care professionals, nor can there be any assurance that upon further examination, the diagnostic company will elect to use these markers.

At present, we are further developing our strategy to include the subsequent validation of gene targets after they are identified through our two platforms. This subsequent validation will make discovered targets significantly more valuable. It will also afford us with the ability to continue the development process in-house and potentially design our own diagnostic tests. To that end, we have identified a number of diseases that hold the greatest promise for future revenues from a diagnostic test. We plan on utilizing our platforms to discover gene targets for these diseases. We will then proceed accordingly.

We will also use our Mexican Subsidiary in conjunction with the Instituto de Biolotecnología, Universidad Nacional Autonoma de Mexico ("IBUNAM"), the premier biotechnology institute in Mexico, for a number of PIVIAT[tm] and PCMAT[tm] projects. Most of these projects will focus on diseases that are problematic to Mexico and Latin America such as cholera and dengue fever. Projects will not only include human diseases but also diseases present in agriculture. As well as applicable problems that are present in the mining industry.

Antibiotics

The cornerstone of our Antibiotics Division is the DPOLT[tm] (Differentially Protected Orthogonal Lantionine Technology) Synthetic Chemistry Platform, which affords us the ability to synthesize a unique class of antibiotics known as lantibiotics.

DPOLT[tm] (Differentially Protected Orthogonal Lantionine Technology)

DPOLT[tm] is a novel organic chemistry synthesis platform that will enable large scale, cost effective production of clinical grade MU1140 and 50 other known lantibiotics. Over the past 80 years, efforts to devise methods to investigate the usefulness of this class of antibiotics have met with uniform failure. DPOLT[tm] is anticipated to lead to 6-10 new antibiotics with novel mechanisms of action. This represents a substantial potential pipeline of antibiotics to replace ones that are currently failing due to the development of bacterial resistance.

As mentioned earlier, we announced the successful synthesis of an antibiotic using our proprietary DPOLT^{tm} technology. The molecule belongs to a class of antibiotics called Lantibiotics that were first discovered over 80 years ago. Although there are now over 50 different Lantibiotics known, this is the first report of a cost-effective method for making one in sufficient amounts and with sufficient purity to enable comprehensive testing and commercial viability.

This initial antibiotic is very closely related to ONI's lead antibiotic, MU 1140, which has the potential to treat a wide variety of infections, including those caused by MRSA and other drug resistant Gram positive bacteria. Domestically, hospital borne infections alone have been on the rise, with an estimated two-million patients contracting dangerous infection annually leading to one-hundred-thousand deaths. Preliminary studies indicate that MU1140 may be the first new antibiotic in 35 years for the treatment of tuberculosis. In addition to MU 1140, this technology will allow us to synthesize all 50 of the known lantibiotics and to conveniently modify their structures in order to improve their usefulness as antibiotics for the treatment of infectious diseases. In effect, DPOLT^{tm} will provide a much needed pipeline of antibiotics at a time when drug resistant bacteria are on the rise.

As a first step in further development, the Company has retained a leading contract manufacturer to refine and scale-up GMP production of the synthetic MU 1140 analog to achieve sufficient quantities for it to be fully tested for regulatory approval. It is estimated that the regulatory process will take a minimum of three years before this drug could become available. Other lantibiotics will follow as they are developed and tested.

Now that we have successfully synthesized our target molecule, we have arranged to have the synthetic version of MU 1140 scaled to production by one of Europe's largest and most reputable peptide manufacturers. This, in turn, should provide ONI with enough synthetic MU 1140 to conduct preclinical testing as well as phase I, II & III FDA clinical trials. Provided the funding for such trials is available. We will also be able to scale production such that it will be sufficient to allow us to commercialize synthetic MU 1140. Once all phases of FDA clinical trials, or equivalent clinical trials required by other regulatory bodies, have been successfully completed and we have received the appropriate approvals to begin marketing.

Replacement Therapy

Our Replacement Therapy Division is centered on SMaRT^{tm} Replacement Therapy, our product for dental caries (tooth decay).

SMaRT^{tm} Replacement Therapy

SMaRT^{tm} Replacement Therapy offers the potential for lifelong protection against dental caries following a single, painless application of a genetically modified bacterial strain to the surfaces of the teeth. This technology is currently approved for FDA phase 1b clinical trials. At present, ONI plans on initiating these trials through its Mexican Subsidiary. We anticipate that phase 1b clinical trials will be approved and begin during the first half of 2009 in Mexico. Management believes that conducting the trials in Mexico provides several potential advantages such as: (1) cost efficiencies, (2) faster regulatory approval, and (3) political expediency. Unlike the US Health Care System, the system in Mexico, as in many other countries, is focused more on preventative medicine due to the extreme costs associated with treatment. SMaRT^{tm} Replacement Therapy is an ideal technology to employ proactively. Approximately 80% of the adult population in the world suffers from diseases of the oral cavity. Problems in the oral cavity often lead to other, related health problems. This is evidenced by recent studies that link poor oral hygiene to cardiovascular disease. We are hopeful that upon registration of the product that appropriate agencies of the Mexican Government or other countries where SMaRT^{tm} is registered will purchase the product for use in public health initiatives.

Global Expansion

ONI's technologies have global implications. To address these implications ONI has developed a comprehensive, global strategy. Although we are domiciled in the United States, we feel that there are numerous advantages in utilizing overseas talent and markets for a variety of our products and technologies.

Some of the initiatives that are currently in progress are:

Mexico

ONI is in the process of establishing a majority owned subsidiary in Mexico, with key Mexican investors prominent in the healthcare and biotech sectors. Our Mexican Subsidiary is expected to be the first of several anticipated Subsidiaries in strategic locations worldwide. Our Mexican Subsidiary is expected to provide the Company a multitude of advantages such as access some of Mexico's top scientists, a more cost effective environment to conduct clinical trials and a regulatory environment where the focus is on the promotion of preventative medicine, which should make our technologies and products more appealing. ONI is in the process of establishing a joint venture with the Instituto de Biolotecnología, Universidad Nacional Autonoma de Mexico ("IBUNAM"), which is the premier biotechnology institute in Mexico. IBUNAM has excellent facilities and a substantial talent base from which the Company can draw. The Mexican subsidiary will also exploit the products and platforms that it is developing, throughout other Central and South American countries.

South America

ONI is exploring partnerships or strategic collaborations in Chile, which may lead to the licensing of its products in Chile or further collaboration similar to that in Mexico.

Europe

ONI expects to also have several initiatives in Europe. For example, the scaling and mass production of Synthetic MU 1140 will be performed by a top-tier European peptide manufacturer. The Company may conduct clinical trials for a number of products in Europe. Lastly, ONI plans on establishing a major marketing initiative in Europe for its Consumer Products. These products would also be expected to be manufactured in Europe.

Mutual Recognition

We are contemplating several strategies that will allow us to leverage our Subsidiaries and expedite or facilitate entry into alternative markets. One such example is through mutual recognition. Our Mexican Subsidiary will utilize Mexican treaty benefits with Spain in furtherance of the commercialization of its products in Spain. Utilizing EU mutual recognition provisions, ONI and its subsidiaries will further commercialize its consumer products and diagnostic platforms in other EU member states.

Research & Development Accounting and Valuation of Intellectual Property

Accounting for research & development (R&D) activities is an area of divergence between U.S. Generally Accepted Accounting Principles (U.S. GAAP) and International Financial Reporting Standards (IFRS). Under U.S. GAAP, all R&D expenditures are charged to expense when incurred. Under IFRS, intangible assets arising from development are recognized if specific criteria are met. Currently, the Financial Accounting Standards Board (FASB), the Securities and Exchange Commission (SEC) and the International Accounting Standards Board (IASB) are in the process of working together to consider the potential convergence of these current accounting standards into a single global standard.

Management believes that several of the Company's technologies (SMaRT^{tm}, M-1140, DPOLT^{tm}, PCMAT^{tm}, PIVIAT^{tm}, Probiora3^{tm}, and LPT3-04^{tm}), had the Company chosen to commercialize in prior years, may have met the technical feasibility requirement under IAS for capitalization of intangible assets. To the extent such international accounting standards would have been applicable to the Company, had the Company chosen to commercialize in prior years, management believes certain of the qualifying costs historically expensed by the Company for research and development of its intellectual property under U.S. GAAP may have been capitalized and recorded as an intangible asset with a corresponding potential increase in stockholders' equity. During this period of time we did not have any material or significant revenues and a significant portion of our expenses consisted of research and development expenses. The application of IAS to the Company's intellectual property research and development expenditures, on a going forward basis, may reduce the losses reported by us under U.S. GAAP due to our recent commercialization of products. Management believes the presentation of this non-GAAP financial information is useful to provide an understanding of how current accounting initiatives, on a going forward basis, may result in a different presentation of the financial condition of the Company from U.S. GAAP.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires us to make estimates and assumptions that affect reported amounts and related disclosures. We consider an accounting estimate to be critical if it requires assumptions to be made that were uncertain at the time the estimate was made; and changes in the estimate or different estimates that could have been made could have a material impact on our results of operations or financial condition. Our financial statements do not include any significant estimates other than stock based compensation that would have a material impact on our results of operations or financial condition.

New Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board ("FASB") issued SFAS No. 157, *Fair Value Measurements* ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. In February 2008, the FASB deferred the effective date of SFAS 157 until the fiscal year beginning after November 15, 2008 for all non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). The partial adoption of SFAS 157 for financial assets and liabilities did not have a material effect on the Company's financial statements. The remaining requirements of SFAS 157 are not expected to have a material effect on the Company's financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* ("SFAS 159"), which gives entities the option to measure eligible financial assets, and financial liabilities at fair value on an instrument by instrument basis, that are otherwise not permitted to be accounted for at fair value under other accounting standards. The election to use the fair value option is available when an entity first recognizes a financial asset or financial liability. Subsequent changes in fair value must be recorded in earnings. This statement is effective as of the beginning of a Company's first fiscal year after November 15, 2007. The adoption of SFAS 159 did not have an effect on the Company's financial statements as it did not elect this fair value option.

In June 2007, the FASB ratified Emerging Issues Task Force Issue No. 06-11, *Accounting for Income Tax Benefits of Dividends on Share-Based Payment Awards* ("EITF 06-11"). EITF 06-11 specifies how companies should recognize the income tax benefit received on dividends that are (a) paid to employees holding equity-classified nonvested shares, equity-classified nonvested share units, or equity-classified outstanding share options and (b) charged to retained earnings under SFAS 123(R). The adoption of EITF 06-11 did not have a material impact on the Company's financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations* ("SFAS 141R"). SFAS 141R establishes principles and requirements for an acquiring entity to recognize and measure in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquired entity and the goodwill acquired. SFAS 141R expands on required disclosures to improve the statement users' abilities to evaluate the nature and financial effects of business combinations. SFAS 141R is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the potential impact, if any, of the adoption of SFAS 141R on its financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements—an amendment of ARB No. 51* ("SFAS 160"). SFAS 160 requires that a noncontrolling interest in a subsidiary be reported within equity and the amount of consolidated net income attributable to the noncontrolling interest be identified in the consolidated financial statements. SFAS 160 calls for consistency in the manner of reporting changes in the parent's ownership interest and requires fair value measurement of any noncontrolling equity investment retained in a deconsolidation. SFAS No. 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS No. 160 is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the potential impact, if any, of the adoption of SFAS 160 on its financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities — an amendment of FASB Statement No. 133* ("SFAS 161"). This statement amends SFAS No. 133 by requiring enhanced disclosures about an entity's derivative instruments and hedging activities, but does not change SFAS No. 133's scope or accounting. SFAS 161 requires increased qualitative, quantitative and credit-risk disclosures about the entity's derivative instruments and hedging activities. SFAS 161 is effective for fiscal years, and interim periods within those fiscal years, beginning after November 15, 2008, with earlier adoption permitted. The adoption of SFAS 161 is not expected to have a material impact on the Company's financial statements.

Results of Operations

Three Months Ended September 30, 2008 and 2007

We had $100,000 in revenues in the three months ended September 30, 2008 compared with $46,584 in revenues in the same period in 2007. The revenue was attributable to NSF SBIR Grant revenue we received for work utilizing our DPOLT^{tm} platform. Our third quarter operating expenses increased by 131.1% to $1,253,200 in the three months ended September 30, 2008 from $542,321 in the same period in 2007. Research and development (R&D) expenses increased 49.5% to $503,685 in the three months ended September 30, 2008 from $337,021 in the same period in 2007. This increase was primarily due to continued work on synthetic MU 1140 using our DPOLT^{tm} platform and our work utilizing our diagnostic platforms. General and administration (G&A) expenses increased 265.1% to $749,515 in the three months ended September 30, 2008 from $205,300 in the same period in 2007, reflecting the shift in corporate focus to commercialization. The increase can be attributed to the Company's recruitment of a new management team, the continued use of outside consultants for business development to help facilitate our marketing plans for our technology.

Interest income increased 79.5% to $15,083 in the three months ended September 30, 2008 from $8,403 during the same period in 2007. This increase is primarily due to the Company's strengthened cash position.

We incurred net losses of $1,138,117 and $487,334 during the three months ended September 30, 2008 and 2007, respectively. The increase in our net loss was principally caused by the increase in general and administrative expenses due to the shift in Company focus from development to commercialization and increases in stock option expense.

Nine Months Ended September 30, 2008 and 2007

We had revenues of $225,000 in the nine months ended September 30, 2008 compared with $106,345 in revenues in the same period in 2007. The revenue was attributable to NSF SBIR Grant revenue we received for work utilizing our DPOLT^{tm} platform. Our operating expenses increased by 87.6% to $3,290,848 in the nine months ended September 30, 2008 from $1,754,022 in the same period in 2007. Research and development (R&D) expenses increased 32.9% to $1,474,725 in the nine months ended September 30, 2008 from $1,109,297 in the same period in 2007. This increase was primarily due to continued work on synthetic MU 1140 using our DPOLT^{tm} platform, our work utilizing our diagnostic platforms, and clinical trials for our LPT3-04^{tm} weight loss product. General and administration (G&A) expenses increased 181.7% to $1,816,123 in the nine months ended September 30, 2008 from $644,725 in the same period in 2007, reflecting the shift in corporate focus to commercialization. The increase can be attributed to the increased cash position due to our financing and the exercise of warrants, and the Company's recruitment of a new management team and the continued use of outside consultants for business development to help facilitate our marketing plans for our technology and from stock option compensation expense.

Interest income increased 29.0% to $29,413 in the nine months ended September 30, 2008 from $22,797 during the same period in 2007.

We incurred net losses of $3,024,865 and $1,624,880 during the nine months ended September 30, 2008 and 2007, respectively. The increase in our net loss was principally caused by the increase in general and administrative expenses due to the shift in Company focus from development to commercialization and increase in stock options expense.

Liquidity and Capital Resources

Since our inception, we have funded our operations through the sale of equity securities in private placement and our initial public offering, the sale of equity securities and warrants in private placements, debt financing and grants. For the nine months ended September 30, 2008, we have received proceeds from the following: (i) award of a two-year $500,000 NSF Phase II grant for our DPOLT technology; (ii) outstanding warrants to acquire 4,536,364 shares of our common stock were exercised which provided $1,996,000 in proceeds to us and resulted in the issuance of 4,536,364 shares of our common stock; and (iii) the sale of 5,777,778 shares of our common stock in a private placement to accredited investors at a price of $0.45 per share resulting in proceeds of $2,600,000 before fees and expenses.

Our operating activities used cash of $2,331,553 for the nine months ended September 30, 2008 and $1,460,732 for the nine months ended September 30, 2007. Our working capital was $2,410,304 as of September 30, 2008. Cash used by operations in the nine months ended September 30, 2008 resulted primarily from our net loss from operations of $3,024,865.

Our investing activities provided net reduction in cash of $9,158 during the nine month period ended September 30, 2008 versus net reduction in cash of $9,861 for the same period ending September 30, 2007.

Our financing activities for the nine months ended September 30, 2008 provided net cash of $4,564,963 from the issuance of shares in private placements, the exercise of warrants, and the financing of insurance premiums. Additional details of our financing activities are provided below:

Private Placement-June 2008

On June 12, 2008, our Securities Purchase Agreement with accredited investors became binding and we closed on $2,600,000 in equity based financing with net proceeds of $2,515,000. We issued a total of 5,777,778 shares of restricted common stock in the private placement. The shares were sold to accredited investors at $0.45 per share. Each participating investor also received warrants to purchase shares of common stock at the price of $1.30 per share. One warrant was issued for each share of common stock issued for a total of 5,777,778 shares that may be acquired upon exercise of the warrants. The warrants are exercisable and expire June 12, 2013. We intend to use the net proceeds of the private placement, including any proceeds from exercise of the warrants, for working capital and general corporate purposes.

Warrant Exercises-Q1 2008

On August 7, 2007, we closed on $1,171,591 in equity based financing. We issued a total of 4,600,000 shares of restricted common stock and warrants to acquire 4,600,000 shares of common stock in a private placement to accredited investors. The shares were sold to accredited investors at $0.25 per share, except that per AMEX requirements, our former CEO, Dr. Ronald Evens acquired his shares at $0.44 per share, which was the closing share price on August 7, 2007. Each warrant to purchase shares of common stock is exercisable at the price of $0.58 per share. The warrants expire on August 8, 2008 (the "August 2007 Warrants"). On January 31, 2008 we amended the August 2007 Warrants, to reduce the exercise price to $0.44, which was the fair market value on the date of the amendment for a designated period of time (from January 28, 2008 to February 29, 2008) following which the exercise price reverted back to $0.58. Prior to the expiration of the August 2007 Warrants, 3,386,364 were issued upon exercise at the amended exercise price resulting in additional working capital proceeds to us of $1,490.000. The remaining unexercised August 2007 warrants expired unexercised on August 8, 2008.

On March 6, 2006, we issued a total of 1,500,000 shares of our common stock and warrants to purchase 1,500,000 shares of our common stock in a private placement to accredited investors. We received gross proceeds of $600,000 in the private placement and incurred estimated costs of approximately $75,000 resulting in net proceeds of approximately $525,000. Each warrant is exercisable on or before February 8, 2008 to acquire one share of common stock at a price of $0.60 per share (the "March 2006 Warrants"). On January 17, 2008 we amended the March 2006 Warrants. Pursuant to the amendment, the warrant exercise price was reduced to $0.44, which was the fair market value on the date of the amendment. Prior to the expiration of the March 2006 Warrants, 1,150,000 were issued upon exercise at the amended exercise price resulting in additional working capital proceeds to us of $506,000. The remaining unexercised March 2006 Warrants expired and are no longer outstanding.

Warrant Exercises Q1 2007

On December 14, 2005, we issued a total of 2,937,500 shares of our common stock and warrants to purchase 2,937,500 shares of our common stock in a private placement to accredited investors. The issuance of the shares of common stock and warrants was made pursuant to the exemptions from registration provided by Section 4(2) of the Securities Act and Regulation D promulgated there under. We received gross proceeds of $1,175,000 in the private placement and incurred estimated costs of approximately $70,000 resulting in net proceeds of approximately $1,105,000. The warrants representing shares of common stock were exercisable by the accredited investors at any time over a two-year period at an exercise price of $0.60 per share. On January 16, 2007, we called all outstanding warrants associated with our December, 2005 private placement pursuant to the terms of the warrant. A total of 1,387,500 warrants were exercised that provided $832,500 in additional working capital and following the call of the warrants no further warrants associated with the private placement remain outstanding.

NSF SBIR Grants

On February 15, 2008, we were awarded a two year NSF SBIR Phase II grant to advance development of its small peptide antibiotic synthesis program using the Company's proprietary DPOLT^{tm}. This federal grant will support studies focused on the synthesis and testing of our lead antibiotic, MU 1140. While the grant will total $500,000, to date we have received $225,000 of these restricted funds with the remaining balance to be issued during the remaining two-year grant period.

Line of Credit

On October 20, 2008, the Company obtained from Signature Bank of New York, a revolving line of credit in the amount of up to $1,000,000, for the purpose of providing working capital to the Company. It is secured by cash collateral of the Company in the same amount deposited with Signature Bank, bears interest at the Prime Rate of Signature Bank, as effective from time to time, and has a final maturity of October 20, 2009. Other than submission of periodic financial information of the Company to Signature Bank, the loan documentation evidencing the revolving line of credit does not contain any financial covenants.

Capital Requirements for Commercialization and Continued Operations

While management is encouraged by the aforementioned financings and revolving line of credit, the available proceeds are insufficient, alone, to regain final compliance with the NYSE Alternext US LLC (formerly known as the American Stock Exchange, hereinafter the "Exchange" or "ASE"), on October 27, 2008 we received a letter from the ASE confirming its intention to proceed with the filing of an application with the Securities and Exchange Commission ("SEC") to delist the common stock of the Company from the Exchange. The notice from the Exchange indicates that the ASE staff has decided that the Company does not meet the following continued listing standards under the ASE Company Guide: Section 1003(a)(ii) in that the Company's stockholders' equity is less than $4.0 million and it has sustained losses in three of its four most recent fiscal years. On October 31, 2008, the Company filed a request to appeal the Exchange's determination and requested a hearing before a panel of the Exchange. As of the date hereof, no date has been set for such hearing, but the hearing is expected to be held within 45 days. During this period, the Company's common stock will continue to be listed on the Exchange pending the outcome of the appeal. The Company plans to appeal and if the Company's position is accepted by the panel, this would allow the Company to continue its listing. Additionally, the Exchange's minimum listing requirements will increase the minimum shareholder equity requirement to $6.0 million at year end. Currently, our plan is to have in excess of $6.0 million in shareholder equity by year end, thereby complying with the continued listing requirements. However, there can be no assurance that we will be able to increase our shareholders equity or that the Company's request for continued listing will ultimately be granted. Also, while the Company is considering alternatives for repositioning itself on other exchanges, including ongoing discussions with potential listing sponsors and market makers, the Company expects that its shares will be listed on another exchange or quoted on a quotation medium prior to any termination in trading on the ASE. Should the Company's appeal be denied, management does believe that following the effectiveness of the Company's delisting, trading in the Company's common stock would be conducted on the OTC Bulletin Board in the United States.

Our business is based on commercializing entirely new and unique technologies, and our current business plan contains a variety of assumptions, expectations and customer adoption rates that are subject to uncertainty, including assumptions and expectations about manufacturing capabilities, clinical testing cost and pricing, regulatory matters, continuing technological improvements, strategic licensing relationships and other relevant matters. These assumptions take into account recent financings, as well as expected but currently unidentified additional financings. We have experienced losses from operations during the last three fiscal years and have an accumulated deficit of $16,995,658 as of September 30, 2008. The net loss from operations for the third quarter of 2008 was $1,138,117. Cash used in operations for the year ended December 31, 2007 was $1,913,760 and for the nine months ending September 30, 2008 was $2,331,553. As of September 30, 2008, our principal source of liquidity was $2,699,760 of cash and cash equivalents. Our current and historical operating results occurred while developing and attempting to commercialize and manufacture products from entirely new and unique technologies. Our business plan requires significant spending related primarily to the commercialization of our consumer products, clinical testing, as well as conducting basic research. These factors place a significant strain on our limited financial resources. Our ultimate success depends on our ability to continue to generate revenue and to raise capital for our operations.

Our capital requirements for the remainder of 2008 will depend on numerous factors, including the success of our commercialization efforts and of our research and development, the resources we devote to develop and support our technologies and the success of pursuing strategic licensing and funded product development relationships with external partners. Subject to our ability to generate income and cash flow from our consumer products and our ability to raise additional capital through joint ventures and/or partnerships, we expect to need to incur substantial expenditures to further commercialize or develop each of our technologies including continued increases in costs related to research, preclinical testing and clinical studies, as well as significant costs associated with being a public company. We will require substantial funds to conduct research and development and preclinical and Phase I clinical testing of our licensed, patented technologies and to develop sublicensing relationships for the Phase II and III clinical testing and manufacture and marketing of any products that are approved for commercial sale. We must generate additional capital resources to enable us to continue as a going concern. Our plans include seeking financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to assure continuation of our operations and research and development programs as well as seeking equity financing.

Our future success depends on our ability to continue to raise capital and ultimately generate revenue and attain profitability. We cannot be certain that additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to us or, if available, will be on terms acceptable to us. If we issue additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current stockholders may experience substantial dilution.

We will continue to seek additional funds for conducting clinical studies for our LPT3-04^{tm} weight loss agent, and the commercialization of ProBiora3^{tm} and LPT3-04^{tm}. As we move into more advanced stages concerning our product development and testing our monthly budget of needed operating capital is likely to increase. Our available working capital at September 30, 2008 is $2,410,304 which includes the proceeds from the financing activities discussed above. While we believe our available working capital is sufficient for us to continue to operate through the next nine months, we expect to continue to need to raise capital to operate beyond this period. If additional capital is not raised, we would likely need to adjust our anticipated plan of operations until we are able to acquire the necessary funds.

ITEM 4T. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act"), that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. We conducted an evaluation (the "Evaluation"), under the supervision and with the participation of our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), of the effectiveness of the design and operation of our disclosure controls and procedures ("Disclosure Controls") as of the end of the period covered by this report pursuant to Rule 13a-15 of the Exchange Act. Based on this Evaluation, our CEO and CFO concluded that our Disclosure Controls were effective as of the end of the period covered by this report.

Changes in Internal Controls

We have also evaluated our internal controls for financial reporting, and there have been no significant changes in our internal controls or in other factors that could significantly affect those controls subsequent to the date of their last evaluation.

PART II – OTHER INFORMATION

ITEM 1A. RISK FACTORS

You should carefully consider the risks described below which update the risk factors contained in our Annual Report on Form 10KSB for the year ended December 31, 2007, as well as the risks described in the risk factors in such form 10KSB before making an investment decision in our securities. These risk factors are effective as of the date of this Form 10-Q and shall be deemed to be modified or superseded to the extent that a statement contained in our future filings incorporated herein by reference modifies or replaces such statement. All of these risks may impair our business operations. The forward-looking statements in this Form 10-Q and in the documents incorporated herein by reference involve risks and uncertainties and actual results may differ materially from the results we discuss in the forward-looking statements. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected. In that case, the trading price of our stock could decline, and you may lose all or part of your investment.

We have a limited operating history with significant losses and expect losses to continue for the foreseeable future.

We have yet to establish any history of profitable operations. Our profitability will require the successful commercialization of one or more of the technologies we either license or own. No assurances can be given when this will occur or that we will ever be profitable.

We may continue to require additional financing in the future

If we are not able to generate sufficient revenues or raise additional capital, among other things:

- We may need to curtail or cease operations and be unable to pursue further development of our technologies;
- We may be unable to pursue patenting some of our technologies and development of our technologies and products;
- We may have to lay-off personnel;
- We could be unable to continue to make public filings;
- We may be de-listed from the American Stock Exchange; and
- Our licenses for our SMaRT™ Replacement Therapy technology and MU 1140 technology could be terminated which would significantly harm our business.

AtSeptember 30, 2008 and December 31, 2007, we had working capital of approximately $2,410,304 and $260,534, respectively. The report of independent registered public accounting firm's report as of and for the year ended December 31, 2007, includes an explanatory paragraph stating that our recurring losses from operations and limited working capital raise substantial doubt about our ability to continue as a going concern. We have an operating cash flow deficit of $2,331,553 for the nine months ended September 30, 2008 and have sustained operating cash flow deficit of $1,913,760 in 2007. Our ability to obtain additional funding may determine our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We can offer you no assurance the government and the public will accept our licensed patented technologies. If they do not, we will be unable to generate sufficient revenues from our technologies, which may cause us to cease operations.

The commercial success of our DPOLT™ platform, SMaRT™ Replacement Therapy, ProBiora3™, LPT3-04™ and other technologies will depend in part on government and public acceptance of their production, distribution and use. Biotechnology has enjoyed and continues to enjoy substantial support from the scientific community, regulatory agencies and many governmental officials in the United States and around the world. Future scientific developments, media coverage and political events may diminish such support. Public attitudes may be influenced by claims that health products based on biotechnology are unsafe for consumption or pose unknown risks to the environment or to traditional social or economic practices. Securing governmental approvals for, and consumer confidence in, such products poses numerous challenges, particularly outside the United States. The market success of technologies developed through biotechnology such as ours could be delayed or impaired in certain geographical areas because of such factors. Products based on our technologies may compete with a number of traditional dental therapies and drugs manufactured and marketed by major pharmaceutical companies and other biotechnology companies. Market acceptance of products based on our technologies will depend on a number of factors including potential advantage over alternative treatment methods. We can offer you no assurance that dentists, physicians, patients or the medical and dental communities in general will accept and utilize products developed from our technologies. If they do not, we may be unable to generate sufficient revenues from our technologies, which may cause us to have to cease operations.

We are subject to the risks of doing business in Mexico and internationally.

We have initiated steps to conduct a joint venture in Mexico through a subsidiary related to the research, development, manufacture, registration, marketing and commercialization of certain of our products. While we anticipate that this joint venture will provide us with certain advantages including reduced costs for clinical trials and access to the Latin American markets, we have no experience in conducting business in Mexico, Latin America or internationally. We may encounter certain risks of doing business in Mexico, Latin America and internationally including:

- differences in protection of our intellectual property rights;
- unexpected changes in, or impositions of, legislative or regulatory requirements;
- political and economic instability;
- fluctuations in foreign exchange rates;
- potential trade restrictions and exchange controls; and
- the burden of complying with foreign laws.

Our exposure to these risks could cause us to be unable to attain the anticipated benefits of our Mexican joint venture and our business could be adversely impacted.

If our expected collaborative partnerships do not materialize or fail to perform as expected, we will be unable to develop our products as anticipated.

We expect to enter into collaborative arrangements with third parties to develop certain products by sublicensing our technologies to strategic partners. We cannot assure you that we will be able to enter into these collaborations or that, if entered, they will produce successful products. If we fail to maintain our existing collaborative arrangements or fail to enter into additional collaborative arrangements, the number of products from which we could receive future revenues would decline.

Our dependence on collaborative arrangements with third parties subjects us to a number of risks. These collaborative arrangements may not be on terms favorable to us. Agreements with collaborative partners typically allow partners significant discretion in electing whether or not to pursue any of the planned activities. We cannot control the amount and timing of resources our collaborative partners may devote to products based on the collaboration, and our partners may choose to pursue alternative products. Our partners may not perform their obligations as expected. Business combinations or significant changes in a collaborative partner's business strategy may adversely affect a partner's willingness or ability to complete its obligations under the arrangement. Moreover, we could become involved in disputes with our partners, which could lead to delays or termination of the collaborations and time-consuming and expensive litigation or arbitration. Even if we fulfill our obligations under a collaborative agreement, our partner can terminate the agreement under certain circumstances. If any collaborative partner were to terminate or breach our agreement with it, or otherwise fail to complete its obligations in a timely manner, our chances of successfully commercializing products would be materially and adversely affected.

We are currently dependent upon a single company to manufacture our products.

Since we currently have no manufacturing facilities, we are dependent upon establishing relationships with independent manufacturers to supply our product needs. We currently rely on one key contract manufacturer as our single source supplier for ProBiora3^{tm} and the Evora^{tm} line of products. If our contract manufacturer is unable or unwilling to produce these products we would not be able to manufacture them until a qualified alternative manufacturer is identified, which could impair our ability to commercialize these products and harm our business. We may not be able to find alternative manufacturers on favorable terms or at all. In addition, competitors who do own their own manufacturing may have an advantage over us with respect to pricing, availability of product and in other areas through their control of the manufacturing process.

Risk Factors Relating to our Common Stock

We may be unable to maintain the listing of our common stock on the NYSE Alternext US (formerly the American Stock Exchange) and that would make it more difficult for stockholders to dispose of their common stock.

Our common stock is listed on the NYSE Alternext US ("ASE"). We cannot guarantee that it will always be listed. The ASE rules for continual listing include minimum market capitalization and other requirements, which we may not meet in the future, particularly if the price of our common stock declines or we are unable to raise additional capital to continue operations.

On April 25, 2007 we received notification from the ASE that we were not in compliance with the ASE's continued listing requirements because our shareholders' equity is less than $2,000,000 and we have experienced losses from continuing operations and/or net losses in two of our most recent fiscal years. We submitted a plan on May 24, 2007 to the ASE for regaining compliance with all of the continued listing standards. On July 2, 2007, the ASE notified the Company that it had completed its review and determined that the Company's compliance plan made a reasonable demonstration of the Company's ability to regain compliance with the continued listing standards by the end of the plan period, October 27, 2008 (the "Plan Period"), and was therefore continuing the Company's listing pursuant to an extension.

On May 14, 2008, the Company received a notice from the ASE that a review of the Company's Form 10-KSB for the year ended December 31, 2007 and Form 10-Q for the period ended March 31, 2008 indicated that it did not meet certain of the ASE's additional continued listing standards. Specifically, the Company was not in compliance with Section 1003(a)(ii) of the Company Guide because its stockholders' equity is less than the required $4,000,000 and because it has losses from continuing operations and net losses in three of its four most recent fiscal years. The Company provided a revised plan of compliance and supporting documentation, dated June 13, 2008, (the "Revised Plan") to the ASE with respect to its previously announced noncompliance with Section 1003(a)(i) of the Company Guide and such Revised Plan was subsequently approved by the ASE subject to compliance by the Plan Period.

On October 27, 2008 the Company received a letter from the ASE confirming the Exchange's intention to proceed with the filing of an application with the Securities and Exchange Commission ("SEC") to delist the common stock of the Company from the Exchange. The notice from the Exchange indicated that the ASE staff decided that the Company did not meet the following continued listing standards under the ASE Company Guide: Section 1003(a)(ii) in that the Company's stockholders' equity is less than $4 million and it has sustained losses in three of its four most recent fiscal years. On October 31, 2008, the Company filed a request to appeal the Exchange's determination and requested a hearing before a panel of the Exchange. As of the date hereof, no date has been set for such hearing, but the hearing is expected to be held within 45 days. During this period, the Company's common stock will continue to be listed on the Exchange pending the outcome of the appeal. The Company intends to provide evidence of compliance which, if accepted by the panel, would allow the Company to continue its listing. However, there can be no assurance that the Company's request for continued listing will ultimately be granted. Also, while the Company is considering alternatives for repositioning itself on other exchanges, including ongoing discussions with potential listing sponsors and market makers, the Company expects that its shares will be listed on another exchange or quoted on a quotation medium prior to any termination in trading on the ASE. Should the Company's appeal be denied, management does believe that following the effectiveness of the Company's delisting, trading in the Company's common stock would be conducted on the OTC Bulletin Board in the United States. This would make it more difficult for stockholders to dispose of their common stock and more difficult to obtain accurate quotations on our common stock. This could have an adverse effect on the price of our common stock. There can be no assurances that a market maker will make a market in our common stock on the OTC Bulletin Board or any other stock quotation system. Furthermore, securities quoted on the OTC Bulletin Board generally have significantly less liquidity than securities traded on a national securities exchange, not only in the number of shares that can be bought and sold, but also through delays in the timing of transactions, reduction in securities analyst and news media coverage, and lower market prices than might otherwise be obtained. As a result, purchasers of shares of our common stock may find it difficult to resell their shares at prices quoted in the market or at all. Furthermore, because of the limited market and generally low volume of trading in our common stock, our common stock is more likely to be affected by broad market fluctuations, general market conditions, fluctuations in our operating results, changes in the market's perception of our business, and announcements made by us, our competitors or parties with whom we have business relationships. Our ability to issue additional securities for financing or other purposes, or to otherwise arrange for any financing we may need in the future, may also be materially and adversely affected by the fact that our securities are not traded on a national securities exchange.

Our stock price historically has been volatile and our stock's trading volume has been low.

Because of the low trading volume and lack of market liquidity, some institutional investors may find it difficult to buy and sell our stock in a sufficiently timely manner, which makes an investment in our Company's stock less appealing. The market price of our common stock has been and is expected to continue to be highly volatile. Factors, including announcements of technological innovations by us or other companies, regulatory matters, new or existing products or procedures, concerns about our financial position, operating results, litigation, government regulation, developments or disputes relating to agreements, patents or proprietary rights, may have a significant impact on the market price of our stock. In addition, potential dilutive effects of future sales of shares of common stock by us and by stockholders, including Fusion Capital, and subsequent sales of common stock acquired by the holders of warrants and options could have an adverse effect on the market price of our shares.

Forward-Looking Statements

This 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements include statements regarding, among other things, (a) our anticipated needs for and availability of working capital, (b) our future financing plans, (c) our strategies, (d) our projected sales and profitability,(e) anticipated trends in our industry. Forward-looking statements, which involve assumptions and describe our future plans, strategies, and expectations, are generally identifiable by use of the words "may," "will," "should," "expect," "anticipate," "estimate," "believe," "intend," or "project" or the negative of these words or other variations on these words or comparable terminology. This information may involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from the future results, performance, or achievements expressed or implied by any forward-looking statements. These statements may be found under "Management's Discussion and Analysis or Plan of Operation" and "Business," as well as in this 10-Q generally. Actual events or results may differ materially from those discussed in forward-looking statements as a result of various factors, including, without limitation, the risks outlined under "Risk Factors" and matters described in this 10-Q generally. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements contained in this filing will in fact occur. In addition to the information expressly required to be included in this filing, we will provide such further material information, if any, as may be necessary to make the required statements, in light of the circumstances under which they are made, not misleading.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

We issued the following restricted securities during the period covered by this report to the named individual pursuant to exemptions under the Securities Act of 1933 including Section 4(2):

On September 1, 2008, we were obligated to issue 1,893 shares of common stock to our consultant, Certified Nutrition for Less, LLC. The obligation to issue the shares was incurred in accordance with the consulting agreement entered into between the Company and the consultant. The price per share was $0.528.

The offering and sale of the common stock was made in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act of 1933 as a transaction by the issuer not involving a public offering.

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 5th day of November, 2008.

ORAGENICS, INC.

BY: /s/ Stanley B. Stein
Stanley B. Stein, President and Chief Executive Officer

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Form	File No	Exhibit	Filing Date	Filed Herewith
4.1	Revolving Line of Credit Agreement between Signature Ban and the Company dated October 20, 2008	8-K	001-32188	10.1	10/24/08	
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).					X
32.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).					X

Exhibit 31.1

CERTIFICATION

I, Stanley B. Stein, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Oragenics, 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 officers 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)) for the registrant and we 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 officers 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 registrant's board of directors (or persons performing the equivalent function):

   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: November 4th, 2008

/s/ Stanley B. Stein

Stanley B. Stein
President (Chief Executive Officer)

Exhibit 31.2

CERTIFICATION

I, David B. Hirsch, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Oragenics, 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 officers 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)) for the registrant and we 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 officers 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 registrant's board of directors (or persons performing the equivalent function):

   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: November 4th, 2008

/s/ David B. Hirsch

David B. Hirsch
Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. Section 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Oragenics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2008 as filed with the Securities and Exchange Commission on the date here of (the "Report"), I, Stanley B. Stein, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in this Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written certification has been provided to the company and will be retained by the company and furnished to the Securities and Exchange Commission or its staff upon request.

Dated this 4th day of November, 2008.

/s/ Stanley B. Stein
Stanley B. Stein
Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. Section 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Oragenics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2008 as filed with the Securities and Exchange Commission on the date here of (the "Report"), I, David B. Hirsch, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in this Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written certification has been provided to the company and will be retained by the company and furnished to the Securities and Exchange Commission or its staff upon request.

Dated this 4th day of November, 2008.

/s/ David B. Hirsch

David B. Hirsch
Chief Financial Officer