

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, 2009.

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**

(State or other jurisdiction of incorporation or organization)

**59-3410522**

(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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark 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 13, 2009, there were 90,866,898 shares of Common Stock, \$.001 par value, outstanding.~~

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**PART I - FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

**Oragenics, Inc.**

**Balance Sheets**

	<u>September 30,</u> <u>2009</u>	<u>December 31,</u> <u>2008</u>
	<u>(Unaudited)</u>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 724,967	\$ 1,165,933
Accounts receivable trade, net	9,876	6,286
Inventory	114,118	11,814
Prepaid expenses and other current assets	<u>113,813</u>	<u>86,666</u>
Total current assets	962,774	1,270,699
Property and equipment, net	<u>117,165</u>	<u>323,424</u>
Total assets	<u>\$ 1,079,939</u>	<u>\$ 1,594,123</u>
<b>Liabilities and Shareholders' Deficit</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 790,835	\$ 1,743,684
Deferred grant revenue	110,267	-
Short term notes payable	<u>71,945</u>	<u>27,687</u>
Total current liabilities	973,047	1,771,371
Long term note payable	<u>1,000,000</u>	<u>-</u>
Total liabilities	1,973,047	1,771,371
Shareholders' deficit:		
Preferred stock, no par value; 20,000,000 shares authorized; none issued and outstanding	-	-
Common stock, \$0.001 par value; 100,000,000 shares authorized; 90,866,898 and 38,316,585 shares issued and outstanding at September 30, 2009 and December 31, 2008, respectively.	90,867	38,316
Additional paid-in capital	24,295,142	19,776,971
Stock subscriptions receivable	(1,000,000)	-
Accumulated deficit	<u>(24,279,117)</u>	<u>(19,992,535)</u>
Total shareholders' deficit	<u>(893,108)</u>	<u>(177,248)</u>
Total liabilities and shareholders' deficit	<u>\$ 1,079,939</u>	<u>\$ 1,594,123</u>

*See accompanying notes.*

**Oragenics, Inc.**

**Statements of Operations  
(Unaudited)**

	<b>Three months ended September 30</b>		<b>Nine months ended September 30</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
Revenues	\$ 199,675	\$ 100,000	\$ 365,842	\$ 225,000
Cost of sales	65,461	-	100,844	-
Gross Profit	134,214	100,000	264,998	225,000
Operating expenses:				
Research and development	427,541	503,685	1,407,516	1,474,725
Selling, general and administrative	1,165,812	749,515	3,883,984	1,816,123
Total operating expenses	1,593,353	1,253,200	5,291,500	3,290,848
Loss from operations	(1,459,139)	(1,153,200)	(5,026,502)	(3,065,848)
Other income (expense):				
Interest income	275	15,083	796	29,413
Interest expense	(24,412)	-	(25,915)	-
Gain on sale of property and equipment	-	-	11,274	4,860
Gain on extinguishment of payables	46,268	-	753,942	-
Local business tax	-	-	(177)	-
Sales tax refund	-	-	-	6,710
Total other income, net	22,131	15,083	739,920	40,983
Loss before income taxes	(1,437,008)	(1,138,117)	(4,286,582)	(3,024,865)
Net loss	<u>\$ (1,437,008)</u>	<u>\$ (1,138,117)</u>	<u>\$ (4,286,582)</u>	<u>\$ (3,024,865)</u>
Basic and diluted net loss per share	<u>\$ (0.02)</u>	<u>\$ (0.03)</u>	<u>\$ (0.08)</u>	<u>\$ (0.09)</u>
Shares used to compute basic and diluted net loss per share	<u>90,439,120</u>	<u>38,317,573</u>	<u>56,071,819</u>	<u>33,975,257</u>

*See accompanying notes.*

**Orogenics, Inc.**

**Statements of Cash Flows  
(Unaudited)**

	<b>Nine months ended</b>	
	<b>September 30</b>	
	<b>2009</b>	<b>2008</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (4,286,582)	\$ (3,024,865)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash bonus paid in common stock	100,000	-
Non-cash services paid in common stock	115,000	-
Non-cash settlement of amounts owed to employees	59,376	-
Depreciation and amortization	198,607	190,565
Stock-based compensation expense	250,690	486,088
Gain on extinguishment of payables	(753,942)	-
Gain on sale of property and equipment	(11,274)	(4,860)
Changes in operating assets and liabilities:		
Accounts receivable, net	(3,590)	-
Inventory	(102,304)	-
Prepaid expenses and other current assets	95,963	(67,566)
Accounts payable and accrued expenses	(102,474)	132,835
Deferred grant revenue	110,267	-
Deferred compensation	(83,333)	(43,750)
Net cash used in operating activities	(4,413,596)	(2,331,553)
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment, net	(9,074)	(51,408)
Proceeds from sale of property and equipment, net	28,000	42,250
Net cash provided by (used in) investing activities	18,926	(9,158)
<b>Cash flows from financing activities:</b>		
Borrowings under short term notes payable	132,556	52,963
Borrowings under long term note payable	1,000,000	-
Payments on short term notes payable	(178,852)	-
Net proceeds from issuance of common stock	3,000,000	4,512,000
Net cash provided by financing activities	3,953,704	4,564,963
Net (decrease) increase in cash and cash equivalents	(440,966)	2,224,252
Cash and cash equivalents at beginning of the period	1,165,933	475,508
Cash and cash equivalents at end of the period	<u>\$ 724,967</u>	<u>\$ 2,699,760</u>
<b>Supplemental disclosure of cash flow information</b>		
Interest paid	<u>\$ 8,042</u>	<u>\$ 54</u>
Non-cash investing and financing activities:		
Stock subscription receivable	<u>\$ 1,000,000</u>	<u>\$ -</u>
Issuance of common stock to employees as settlement of amounts owed	<u>\$ 205,032</u>	<u>\$ -</u>
Borrowings under short term notes payable for prepaid expense	<u>\$ 123,112</u>	<u>\$ -</u>

*See accompanying notes.*

**Oragenics, Inc.**

**Notes to Financial Statements  
(Unaudited)**

1. Organization and Significant Accounting Policies

Oragenics, Inc. (the "Company") 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, 2009 and December 31, 2008 and for the three and nine months ended September 30, 2009 and 2008 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, 2009 are not necessarily indicative of the results that may be expected for the year ended December 31, 2009 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, 2008, which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 1, 2009. 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. Although the Company currently believes that it will have sufficient resources to commercialize selective products, it intends to seek additional funding to further develop and commercialize other products.

**Adoption of New Accounting Standards**

On July 1, 2009 the Financial Accounting Standards Board ("FASB") Accounting Standards Codification™ ("ASC") became the authoritative source of accounting principles to be applied to financial statements prepared in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). In accordance with the ASC, citations to accounting literature in this report are to the relevant topic of the ASC or are presented in plain English. This standard is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Company adopted this standard at its effective date.

**Revenue Recognition**

The Company recognizes revenue from the sales of product when title and risk of loss pass to the customer, which is generally when product is shipped. Grant revenues are recognized as the reimbursable expenses are incurred over the life of the related grant. Grant revenues are deferred when reimbursable expenses have not been incurred.

**Inventory**

Inventories are stated at the lower of cost or market. Cost, which includes material, labor and overhead, is determined on a first-in, first-out basis.

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.

ASC 740, *Income Taxes*, 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. ASC 740 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. ASC 740 was adopted by the Company effective January 1, 2007. The Company recognized a \$252,827 increase in the liability for unrecognized tax benefits that are related to research and development credits, which was accounted for as a reduction to the January 1, 2007 balance of the deferred tax asset and related valuation allowance. The entire amount of this unrecognized tax benefit, if recognized, would result in an increase to the deferred tax asset valuation allowance, and would not have an impact on the effective tax rate.

The Company files its income tax returns in the U.S. federal jurisdiction and in Florida. With few exceptions, the Company is no longer subject to federal or state income tax examinations by tax authorities for years before 2003.

### 4. Fair Value of Financial Instruments

ASC 820, *Fair Value Measurements and Disclosures*, defines fair value, provides guidance for measuring fair value and requires certain disclosures. This standard discusses valuation techniques, such as the market approach (comparable market prices), the income approach (present value of future income or cash flow), and the cost approach (cost to replace the service capacity of an asset or replacement cost). The standard utilizes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The following is a brief description of those three levels:

*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, 2009. 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, 2009.

### 5. Stock Options Expense During the 3rd Quarter, 2009

During the 3rd quarter, no stock options were issued and there were 2,340,000 options forfeited due to employee layoffs, employee separations and Board member departures. On August 13, 2009, the compensation committee approved the acceleration of the vesting of certain outstanding option awards, the vesting of which was tied to our share price reaching certain levels in the future. Option awards previously made to Mr. David Hirsch, our President and Chief Executive Officer, Dr. Jeffrey Hillman, our Chief Science Officer and certain other Company employees were impacted by the accelerated vesting of these options (433,333 shares for Mr. Hirsch, 500,000 shares for Dr. Hillman, 563,333 for other Company employees). Following the acceleration of vesting by the compensation committee, Mr. Hirsch's grant of options to acquire 500,000 shares of our common stock at \$0.49 per share is now fully vested and exercisable (including the 433,333 shares impacted by the acceleration of vesting), Dr. Hillman's grant of options to acquire 700,000 shares of our common stock at \$0.85 per share is now fully vested and exercisable (including the 500,000 shares impacted by the acceleration of vesting). All other terms of the prior option awards, including the share amounts covered by the options and exercise prices remained the same.

From January, 1, 2009 to the date of this filing, 1,736,665 stock options previously granted have vested and 2,340,000 have been forfeited. Stock option compensation expense of \$250,690 was recorded and is a non-cash expense. This amount is included in research and development and selling, general and administrative expenses in the accompanying statement of operations.

#### 6. Common Stock Issued During the 3rd Quarter, 2009

In September, the Company issued 500,000 shares of restricted common stock to Media4Equity LLC ("M4E") pursuant to an agreement whereby Media4Equity will provide consulting services to us with respect to national media exposure of placements of print and radio features. The agreement was made effective on September 3, 2009 and also requires us to pay a monthly fee to M4E of \$10,000 during the three year term of the agreement, subject to certain termination rights. The shares of common stock have a fair market value of \$115,000 based on a price of \$0.23 per share. This amount is included in selling, general and administrative expenses in the accompanying statement of operations.

#### 7. Short Term Notes Payable

In July, we entered into a short term note payable for \$70,023 with an interest rate of 5.75% to finance our directors and officers liability insurance. This note matures on May 24, 2010.

In August, we repaid a short term note in full to an accredited investor in the amount of \$100,000 plus outstanding accrued and unpaid interest thereon. The note was issued on April 15, 2009 and had a maturity date of April 15, 2011 with an interest rate of 15% per annum.

#### 8. Outstanding Warrants and Stock Options

As of the date of this filing there are approximately 7,127,778 warrants outstanding and there are approximately 2,330,000 stock options have been granted that have not been forfeited. The total number of outstanding warrants and unexercised stock options is 9,457,778. If all warrants and stock options were exercised, the total number of outstanding shares would be approximately 100,324,676. This share amount exceeded the number of shares of common stock authorized in our Articles of Incorporation as of September 30, 2009. We held a shareholder meeting on October 28, 2009 and our shareholders voted to amend our Articles of Incorporation to increase our authorized shares of common stock to 300,000,000.

#### 9. Entry into a Material Definitive Agreement

On June 29, 2009, the Company entered into and consummated a private placement of equity and debt financing pursuant to a Securities Purchase Agreement (the "Securities Purchase Agreement") with an accredited investor. Pursuant to the terms of the Securities Purchase Agreement the Company issued 50,000,000 shares of its Common Stock to the Koski Family Limited Partnership ("KFLP") and warrants to the KFLP to acquire 1,000,000 shares of Company common stock at an exercise price of \$0.10 per share in exchange for \$4,000,000, the payment of which consisted of the following: \$1,500,000 in cash at closing and \$2,500,000 pursuant to a non-interest bearing promissory note providing for five consecutive monthly installment payments of \$500,000 commencing July 31, 2009. The promissory note was recorded as a stock subscription receivable and shown as a reduction to shareholders' equity. KFLP also provided a secured loan of \$1,000,000 to the Company. The loan is secured by substantially all of the Company's assets (excluding receivables) and bears interest at the rate of Prime plus 4.0% which is payable quarterly. The principal of the loan is due in five years. The warrants expire in five years and are immediately exercisable.

As a result of the transaction the board of directors believes there was a change of control of the Company with the KFLP acquiring a controlling interest of approximately 56.6 % of our outstanding voting common stock. Two Koski family members, Robert C. Koski and Christine L. Koski were appointed to our Board of Directors. In addition, following the transaction, the KFLP also has the ability to consent to the selection and appointment of two outside directors.



The KFLP was also granted registration rights in connection with any offerings by the Company of its shares. Such registration rights require the Company to include a certain amount of the KFLP shares in a Company offering determined based upon 15% of the shares to be publicly offered.

In connection with, and as a condition to the Securities Purchase Agreement, the purchasers, including George Hawes our largest shareholder prior to this transaction, under that certain securities purchase agreement dated June 12, 2008, (the "Hawes Agreement") entered into waiver and release agreements with us. In addition, such individuals waived and relinquished any special rights they possessed pursuant to agreements with the Company, including, but not limited to, (i) rights of first refusal (ii) antidilution regarding future equity sales and (iii) covenants regarding secured lending. In connection with such waivers and releases, warrants to acquire 3,220,000 shares of our common stock at an exercise price of \$1.30 per share that were previously issued under the Hawes Agreement were subject to the right of exchange for new replacement warrants to acquire the same number of shares under the same terms except for a change in the exercise price from \$1.30 to \$0.75.

In addition to the above, as a further condition to the consummation of the transaction contemplated by the Securities Purchase Agreement the Company was required to obtain satisfactory arrangements with three main creditors for reductions in the amounts payable by the Company to such creditors. As of June 29, 2009 the agreed upon reductions in accounts payable with such creditors amounted to \$707,674 in aggregate and the reductions were conditioned upon prompt payment of the remaining balances owed to such creditors after taking into account the reductions agreed to by such creditors. Further reductions to amounts owed to creditors were agreed to during the three months ending September 30, 2009 in the amount of \$46,268. The total amount of reductions for the nine months ending September 30, 2009 was \$753,942 which was recorded as a gain on extinguishment of payables and reported as Other Income.

#### 10. Subsequent Events

On October 28, 2009 at our annual shareholder meeting our proposal to amend the Company's articles of incorporation to increase the authorized shares of common stock from 100,000,000 to 300,000,000 was approved by shareholders and the amendment to our articles of incorporation was filed with the Florida Department of State. In addition, at our annual meeting our shareholders also approved a second amendment to our Amended and Restated 2002 Stock Option and Incentive Plan to increase the shares available for grant thereunder from 5,000,000 to 12,500,000. The Company reviewed for subsequent events through November 13, 2009.

## 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.*

### Overview

We are a multi-faceted biopharmaceutical company focused on the discovery, development and commercialization of a variety of products and technologies. We are currently transitioning from a company with a historic focus on research and development to a company with increased focus on immediate and long term commercialization.

We generate revenue through the sale of our consumer healthcare products. We are optimistic about the ongoing level of interest we are experiencing with our lead branded consumer healthcare products at this time. As our Probiora3 and EvoraPlus manufacturing, marketing and selling initiatives progress, we expect to continue to experience a higher level of overall expenses associated with such efforts as well as with the continued development of our technologies. We expect the current increases in our expenses to continue into the near future as we fully implement the initiatives we have underway.

Our goal is to achieve positive operational cash flow as quickly as possible by allocating most of our resources on the commercialization or monetization of technologies that can provide revenues in the near term. This initially means that our first priority will be to focus the bulk of our resources on the Consumer Healthcare Division. We will also seek opportunities in Biomarker Discovery that either provide up-front money or fee-for-service arrangements. Concurrently, we expect to seek additional capital to accelerate the development of our technologies. While we are pursuing these priorities, we expect to simultaneously make incremental progress in Antibiotics, Biomarker Discovery and Biologics until they reach an inflexion point and can be monetized. The pace of any incremental progress we may achieve, however, will be based on the amount of our limited available capital resources we are able to allocate to each individual technology. If we are able to obtain sufficient additional capital, the pace of progress would be expected to increase. Once we begin to monetize our current technologies, we will also be able to commit greater capital to further research and development alternative technologies that are in alignment with our vision and strategic goals.

### Financial Strategy

Since our inception, we have funded a significant portion of our operations from the public and private sales of our securities. Furthermore, we have not earned significant revenue from operations during the last two years. Until recently most of our revenue has been from sponsored research agreements and various governmental grants. We will require additional capital to fund our business operations and we continue to seek additional capital to effectuate our business plans. The further development, testing and commercialization of our technologies, individually and in the aggregate, are expected to be costly to undertake and complete and will require additional capital over and above what we currently have available to us. Our current available capital limits our ability to fully develop our technologies. We expect to allocate our limited capital resources to the development of our technologies while we continue to explore additional capital raising opportunities. There can be no assurances that such additional capital will be available to us or on favorable terms or at all. The time periods for the expected continued development of our technologies have been extended from those previously indicated by us from time to time due primarily to our insufficient capital position. The time periods for expected developments could also change in the future depending on the progress of our ability to negotiate a partnering arrangement, as well as our efforts to raise additional capital.

Although we have started to earn revenue from the sales of our Consumer Healthcare products and technologies, revenue to date has been modest. Our objective is that the revenue from Consumer Healthcare products will be able to fully and sufficiently support the continued operations of the Consumer Healthcare Products Division. We anticipate additional purchase orders and/or revenue from the sale of EvoraPlus<sup>TM</sup>, our oral probiotic for adults, during the remainder of the current calendar year and we are optimistic about the prospects for Teddy's Pride<sup>TM</sup>, our oral probiotic for the companion pet market. We also anticipate that, we will have opportunities to partner with or license some of our technologies to larger global companies. We hope to be able to negotiate upfront payments in connection with these potential partnerships and/or licenses.

## Operational Strategy

We have a number of products and platforms. These products and platforms are structured and viewed by us as four distinct Divisions:

(1) Consumer Healthcare, which consists of ProBiora3™, the EvoraPlus™, Teddy's Pride™ and EvoraKids™ as well as the LPT3-04™ weight loss agent;

(2) Biomarker Discovery (formerly referred to by us as "Diagnostics"), which consists of the PIVIAT™ and PCMAT™ platforms;

(3) Antibiotics, which consists of our lead antibiotic, MU 1140, and the DPOLT™ antibiotic synthesis platform; and

(4) Biologics (formerly referred to by us as "Replacement Therapy"), which consists of our SMaRT™ Bacterial Replacement Therapy technology.

Because we have limited capital and human resources, we cannot pursue commercialization and further development of each and every technology that we own simultaneously. As such, we have decided to pursue a strategic course that focuses the majority of our resources towards those technologies that present the best opportunity to generate revenue for the Company in the short-term. The allocation of resources is determined by us on a case-by-case basis and is subject to periodic review. Currently, we are rolling out products in our Consumer Healthcare Division and most of our resources are being deployed in support of that endeavor. However, we expect to continue to commit our remaining available resources to our other three divisions. As the Consumer Healthcare Division matures and begins to generate meaningful revenue and is able to become self-sustaining, we anticipate being able to allocate greater resources to the other divisions. We believe that each of our products and platform technologies addresses potentially large market opportunities.

### Consumer Healthcare - Operational Highlights

We believe we are making progress in our Consumer Healthcare Division. Set forth below are some of the highlights of our progress.

#### Large Retailers - The Drugstore & Big Box Retail Channels:

We are in discussions with several large drugstore and big box retailers regarding our Consumer Healthcare products. The process for product adoption by large retailers typically has five essential phases; (1) the incorporation of a product into a retailer's "planagram", (2) the assignment of a "vendor ID" to the vendor and the establishment of connectivity, typically using electronic data interchange, (3) the transmission and receipt of an initial order, (4) the fulfillment and delivery of the initial order, and (5) the subsequent re-order by the retailer to replenish inventory. In early November 2009, we received written confirmation that EvoraPlus™ would be included in the planagram of one of the nation's largest drugstore chains. In connection with our efforts with this drugstore chain, we have established a vendor ID. We currently anticipate we will receive an initial order from this potential customer sometime in the first quarter of 2010 and that the order would be fulfilled and delivered shortly thereafter. However, this retailer can, at its sole discretion, change its planagram at any time. Therefore, there can be no assurances that we will in fact receive the anticipated initial order. Also, should we receive, fulfill and deliver an initial order from this prospective customer, there can be no assurances that we will receive subsequent re-orders. We expect to be coming to decision points with other prospective retail customers in the coming weeks and we are optimistic about our prospects.

#### Grocery Store Channel:

We are in discussions with several grocery store chains including some of the largest grocery chains in the United States. During the last several weeks we received orders from several large regional grocery store chains. We are optimistic about the potential opportunities for our products in this channel, there can be no assurances, however, that our products will be successfully received by the marketplace through this channel.

#### Private Label Channel:

Our first private label customer, Garden of Life, formally launched its first private label product containing ProBiora3 from Orogenics. Garden of Life has since placed subsequent orders for their private label product using ProBiora3 and they have placed initial orders for a similar private label product for the pet market. It is also anticipated that they will begin rolling out a children's product in early 2010.

#### Trade Show:

In mid-November, we exhibited our products at the Supply-Side West trade show, which is one of the largest raw material / ingredient shows in the world. We experienced a substantial amount of interest from a number of company representatives in attendance at the show and we are optimistic about the potential for future business arising from such initial interest.

#### Media Exposure:

In July, a segment on EvoraPlus appeared on Fox News throughout the United States. This segment was followed by a subsequent segment that aired on November 4, 2009 on Fox News. We believe this media coverage was beneficial for us in our efforts to gain market traction and acceptance of our consumer healthcare products.

#### International Interest:

We have experienced an increase in interest and demand for our consumer products internationally. To address such interests, we have retained a Director of International Sales and Marketing with substantial international marketing experience and we remain optimistic about potential future developments from this channel.

### **Technology Descriptions and Objectives**

#### **Consumer Healthcare**

The specific goal for our Consumer Healthcare division is to rapidly and effectively commercialize ProBiora3<sup>TM</sup> and LPT3-04<sup>TM</sup>.

**ProBiora3<sup>TM</sup> (Probiotics).** ProBiora3<sup>TM</sup> contains three naturally occurring, live microorganisms that help 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> in reducing the levels of specific bacteria in the mouths of young, healthy adult subjects.

We have developed a bifurcated strategy whereby we have established a separate brand for the active ingredient, ProBiora3<sup>TM</sup>, and we have developed the three house brand names below. Our house brands contain different ratios, or blends, of the three natural strains contained in ProBiora3<sup>TM</sup> and potentially different delivery mechanisms such that each product will be tailored to the needs of specific markets. The products currently in production or the product pipeline are:

- **EvoraPlus<sup>TM</sup>**

a product with equal weight of all three strains that is optimally designed for the general consumer market.

- **Teddy's Pride<sup>TM</sup>**

a product that has a mixture which focuses primarily on promoting breath freshening and tooth whitening in companion pets.

- **EvoraKids<sup>TM</sup>**

a product that has a greater concentration of the ProBiora3 strain designed to promote dental health, which is more of an issue for children.

Other house products with different formulations and delivery systems are also planned. EvoraPlus™ was the first product to market. EvoraPlus™ is 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™. We have completely outsourced the manufacturing and fulfillment processes. Our manufacturer is a large, Good Manufacturing Practices certified manufacturer with the ability to scale production to meet our expected needs. We recently announced the launch of Teddy's Pride™. Teddy's Pride™, our product for the companion pet market, comes in a powder form and is contained in a small pale that holds a 60-day supply and is administered by sprinkling a specific dose on the pet's food once per day.

*Marketing Progress.* We believe we are starting to gain acceptance with our first product, EvoraPlus™ and we are starting to see traction with Teddy's Pride™, our product for the companion pet market. Although our progress has been somewhat slower than anticipated for a variety of reasons, we remain optimistic about the future prospects for these products.

Our initial efforts to drive sales of our house products through the production of a one-minute television spot have been delayed. Initial testing of our spot ad was not satisfactory. However, we expect to re-format our spot ad with a new version that we anticipate will be more successful in generating demand for our products. However, our ability to purchase adequate media time may be limited due to a lack of available capital resources.

We believe we have made significant progress in our efforts to generate interest in the sale or licensing of ProBiora3™ as an active ingredient. We continue to engage in meaningful discussions with several large, global consumer products companies who are interested in incorporating the technology into products already in the stream of commerce. Many of these products are well known and used by millions of people on a daily basis.

Despite our efforts to sell our house products and commercialize ProBiora3™, 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™.** LPT3-04™ 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™ is orally available, and we believe it has an excellent safety and tolerability profile. As with ProBiora3™, LPT3-04™ 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™ 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™. We anticipate that this process will be complete by the end of 2009. Once this has been accomplished, we plan on initiating subsequent and more comprehensive human trials, which, once commenced, should last approximately four to five months. If the results are satisfactory, we will initiate marketing efforts immediately thereafter; however there can be no assurances that the results of our contemplated clinical trials will prove successful.

### **Biomarker Discovery**

The goal of our Biomarker Discovery unit is to utilize the PIVIAT™ and PCMAT™ 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™ and PCMAT™***

Proteomics-based *In Vivo* Induced Antigen Technology (PIVIAT™) 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™ gene targets.

Proteomics-based Change Mediated Antigen Technology (PCMAT™) is a platform technology that was derived from and greatly extends the potential applicability of PIVIAT™. This technology rapidly identifies proteins (and their genes) that are expressed when a cell undergoes any sort of change. PCMAT™ 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™ 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™ 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™ diagnostic platform, we have discovered what we believe to be unique genetic markers that appear during the earliest stages of colorectal cancer. As announced last summer, we 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™ 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. We anticipate that the diagnostics company will finish validation by the end of the fourth quarter, 2009, at which point they will likely make a decision on whether to include our targets into a diagnostic test. If they choose to do so, our agreement provides for the payment of milestone fees upon the filing of a 510K application with the FDA.

We have identified a number of diseases that hold the greatest promise for future revenues from a diagnostic test using gene targets. We plan on utilizing our platforms to discover gene targets for these diseases. We anticipate that we will begin this process by the end of the fourth quarter, 2009.

## **Antibiotics**

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

***DPOLT™ (Differentially Protected Orthogonal Lantionine Technology).*** DPOLT™ 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™ 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™ 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 our 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 MU 1140 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™ 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 antibiotics will follow as they are developed and tested.

Last fall, we announced that we were successful in using the DPOLT™ platform to synthetically produce an analog of the MU 1140 molecule. We are now in the process of having the synthetic version of MU 1140 scaled to production by Almac Sciences, one of Europe's largest and most reputable peptide manufacturers. This endeavor is more than half way complete and we anticipate the process of scaling MU 1140 should take an additional four to five months to complete. This, in turn, should provide us with enough synthetic MU 1140 to conduct preclinical testing. Once preclinical testing is complete, we will seek partnership and/or licensing opportunities with major pharmaceutical companies with the intent to fund subsequent phase I, II & III FDA clinical trials.

## Biologics

Our Biologics Division is centered on SMaRT™ Replacement Therapy, our product for dental caries (tooth decay).

**SMaRT™ Replacement Therapy.** SMaRT™ Replacement Therapy™ is a professional/Rx product intended for the prevention of dental caries (tooth decay). Dental caries remain a major health problem afflicting a majority of the population in the United States and worldwide. Lactic acid production by the oral bacterium *Streptococcus mutans* has long been known to be integral to the pathogenic process for dental caries. Oragenics Inc.'s replacement therapy technology replaces the indigenous, acid-producing *S. mutans* with a SMaRT™ effector strain, which has been genetically modified so as not to produce the acid associated with caries formation.

The wild-type *S. mutans* originally used for construction of the SMaRT strain was isolated from a human subject and was carefully selected based on its ability to produce the antibiotic, MU1140. MU1140 has been shown to kill all other strains of *S. mutans* that it has been tested against. The SMaRT™ effector strain was generated by transforming this wild-type parent strain with recombinant DNA that introduced a large deletion mutation in the gene for lactate dehydrogenase (LDH) eliminating the strain's ability to produce lactic acid.

Our SMaRT™ effector strain for the replacement therapy of dental caries has the following advantages over existing decay-prevention technologies: (1) a single treatment regimen involving application of SMaRT™ cells onto patients' tooth surfaces using a cotton tipped swab for five minutes has the potential to provide lifelong protection against most tooth decay; (2) the possibility of deleterious side-effects are negligible since the effector strain is essentially identical to the microorganism which is found universally on the teeth of humans; (3) minimal patient education and compliance is required.

SMaRT™ 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, our plans are to initiate phase 1b trials once adequate financing has been achieved. We anticipate the cost of conducting phase 1b to be under \$1M. We also anticipate that phase 1b trials will take less than six months to complete. Once phase 1b trials have been completed and safety has been established, we plan on seeking partnerships and/or licensing arrangements with major pharmaceutical companies. It would be our intent to use these partnerships and/or licensing arrangements to fund subsequent clinical trials, which we anticipate will be costly and may take several years to complete.

## Global Expansion

Although we are domiciled in the United States, we believe there are opportunities and advantages in utilizing foreign talent and markets for a variety of our products and technologies. While we have established a subsidiary in Mexico and embarked upon other global strategic initiatives, we are currently reviewing and evaluating our global strategic plans given our limited capital resources and the costs associated with such efforts and the expected benefits.

## Critical Accounting Estimates

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 October 2009, the FASB issued ASU No. 2009-13, "Revenue Recognition (ASC Topic 605) — Multiple-Deliverable Revenue Arrangements." ASU No. 2009-13 addresses the accounting for multiple-deliverable arrangements to enable vendors to account for products or services (deliverables) separately rather than as a combined unit. This guidance establishes a selling price hierarchy for determining the selling price of a deliverable, which is based on: (a) vendor-specific objective evidence; (b) third-party evidence; or (c) estimates. This guidance also eliminates the residual method of allocation and requires that arrangement consideration be allocated at the inception of the arrangement to all deliverables using the relative selling price method. In addition, this guidance significantly expands required disclosures related to a vendor's multiple-deliverable revenue arrangements. ASU No. 2009-13 is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010 and early adoption is permitted. A company may elect, but will not be required, to adopt the amendments in ASU No. 2009-13 retrospectively for all prior periods. Management is currently evaluating the requirements of ASU No. 2009-13 and has not yet determined the impact on the Company's financial statements.

In August 2009, the FASB issued ASU 2009-05, "Fair Value Measurements and Disclosures (ASC Topic 820) — Measuring Liabilities at Fair Value" ("Update 2009-05"). Update 2009-05 provides clarification regarding valuation techniques when a quoted price in an active market for an identical liability is not available in addition to treatment of the existence of restrictions that prevent the transfer of a liability. Update 2009-05 also clarifies that both a quoted price in an active market for an identical liability at the measurement date and the quoted price for an identical liability when traded as an asset in an active market (when no adjustments to the quoted price of the asset are required) are Level 1 fair value measurements. This standard is effective for the first reporting period, including interim periods, beginning after issuance. Adoption of Update 2009-05 did not have a material effect on Company's financial statements.

## Results of Operations

### *Three Months Ended September 30, 2009 and 2008*

We had \$199,675 in revenues in the three months ended September 30, 2009 compared with \$100,000 of revenues in the same period in 2008. The revenue was generated from \$ 85,372 of EvoraPlus product sales and \$114,303 of grant revenue recorded during the quarter. In the quarter, deferred grant revenue was recorded in the amount of \$110,267. This amount represents the NSF SBIR Phase II grant for the small peptide antibiotic synthesis program using our proprietary DPOLT<sup>tm</sup> in the amount of \$86,374 and the University of Florida grant to identify disease-specific proteins expressed during citrus greening using our proprietary PCMAT in the amount of \$23,893.

Cost of sales of \$65,461 were recorded in the three months ended September 30, 2009 compared with no cost of sales in the same period in 2008. These costs include the production and manufacture of our Consumer Healthcare products totaling \$33,627. Cost of sales also includes shipping and processing expenses of \$21,200. This amount includes one-time costs to relocate inventory from our order fulfillment center in New York to a new fulfillment center in California, costs to enhance our order processing services and higher shipping expenses due to an increase in our manufacturing vendor supply chain. Cost of sales also includes scrap expense of \$10,634 which represents the replacement of inventory in July with our new improved EvoraPlus product.

Our third quarter operating expenses consist of Research and Development (R&D) expenses and Selling, General and Administrative (SG&A) expenses. Our operating expenses increased by 27.1% to \$1,593,353 in the three months ended September 30, 2009 from \$1,253,200 in the same period in 2008. R&D expenses decreased 15.1% to \$427,541 in the three months ended September 30, 2009 from \$503,685 in the same period in 2008. Even though total R&D expenses declined, stock options expense increased by \$93,887 as a result of the acceleration of vesting of options. Compared to the same period in 2008, R&D expenses reflect reductions in salaries and fringe costs as a result of the decrease in staff by \$54,950, reduced consulting fees by \$51,967, lower royalty expenses by \$32,108, lower supplies of \$26,536 and reductions in legal patent expenses of \$17,428. S,G&A expenses increased 55.5% to \$1,165,812 in the three months ended September 30, 2009 from \$749,515 in the same period in 2008. The increase over the prior period was due to advertising expense of \$226,752 which includes the issuance of common stock to Media4Equity with a fair market value of \$115,000. Stock option expense increased by \$92,299 as a result of the acceleration of vesting of certain outstanding options and the addition of sales staff and associated expenses by \$193,582 which was offset by a decrease in investor and public relation expenses totaling \$111,402.



Other income of \$22,131 increased by \$7,048 for the three months ended September 30, 2009. Other income included the gain on extinguishment of payable of \$46,268 due to the reduction in expenses owed to several creditors following the June 29, 2009 financing transaction. Interest expense for the three months ended September 30, 2009 totaling \$24,412 represents interest expense for the short term note with an accredited investor that was repaid during the quarter, and accrued interest expense on the long term note with the Koski Family Limited Partnership which was part of the June 29, 2009 financing transaction. Interest income decreased by \$14,806 in the three months ended September 30, 2009 compared to the same period in 2008. This decrease is primarily due to the Company's reduced cash position during the third quarter resulting from use of cash to pay amounts owed following the June 29, 2009 financing transaction with the KFLP.

We incurred net losses of \$1,437,008 and \$1,138,117 during the three months ended September 30, 2009 and 2008, respectively. The increase in our net loss was principally caused by the increase in sales and marketing expenses, acceleration of options expense and the issuance of common stock to Media4Equity.

#### ***Nine Months Ended September 30, 2009 and 2008***

We had \$365,842 in revenues in the nine months ended September 30, 2009 compared with \$225,000 in revenues in the same period in 2008. EvoraPlus product revenues totaled \$151,539 and grant revenues were \$214,303. Grant revenue was generated from the National Science Foundation (NSF) Phase II grant for work utilizing the Company's proprietary DPOLT™ technology in the amount of \$176,108 and with the University of Florida to identify disease-specific proteins expressed during citrus greening in the amount of \$38,195.

Cost of sales of \$100,844 were recorded in the nine months ended September 30, 2009 compared with no cost of sales for the same period in 2008. Our cost of sales represents costs in connection with the production and manufacture of our Consumer Healthcare products totaling \$60,163, shipping and processing costs of \$26,714 and scrap costs in the amount of \$13,967.

Our operating expenses increased by 60.8% to \$5,291,500 in the nine months ended September 30, 2009 from \$3,290,848 in the same period in 2008. R&D expenses decreased by 4.6% to \$1,407,516 in the nine months ended September 30, 2009 from \$1,474,725 in the same period in 2008. R&D expenses declined due primarily to the reduction in stock options expense of \$179,829. S,G&A expenses increased 113.9% to \$3,883,984 in the nine months ended September 30, 2009 from \$1,816,123 in the same period in 2008. The increase can be attributed to the Company's hiring of a new management and new sales team totaling \$522,353 in salaries and fringe benefits. Consulting fees for investor relations increased by \$578,982 due to the need for several investment firms to assist with our cash raising activities. Legal fees increased by \$568,042 to support rights offering initiative, the Alternext Paris exchange and services to expand our global business in Mexico and France. Marketing and advertising costs increased by \$377,867 for our EvoraPlus and Teddy's Pride products.

Other income of \$739,920 increased by \$698,937 for the nine months ended September 30, 2009. Other income included the gain on extinguishment of payable of \$753,942 due to the reduction in expenses owed to three creditors that was agreed to in connection with the June 29, 2009 financing transaction plus additional creditor reductions realized during the 3rd quarter. Gain on the sale of equipment for the nine months ended September 30, 2009 totaling \$11,274 represents the sale of equipment no longer needed to support on-going Mutacin research. Interest expense for the nine months ended September 30, 2009 totaling \$25,915 is primarily interest expense for the short term note with an accredited investor and interest expense for the long term note with the Koski Family Limited Partnership which was part of the June 29, 2009 financing transaction. Interest income decreased \$28,617 in the nine months ended September 30, 2009 from \$29,413 during the same period in 2008. This decrease is primarily due to the Company's reduced cash position and cash settlements made following the Koski Family investment.

We incurred net losses of \$4,286,582 and \$3,024,865 during the nine months ended September 30, 2009 and 2008, respectively. The increase in our net loss was principally caused by the increase in S,G&A expenses.

## 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 first nine months of 2009, we have received \$200,000 of restricted funds as part of the \$500,000 NSF Phase II grant to advance development of its small peptide antibiotic synthesis program using our proprietary DPOLT<sup>tm</sup>. This federal grant will support studies focused on the synthesis and testing of our lead antibiotic, MU 1140. During the 3rd quarter, we have received \$124,570 from the University of Florida under the prime grant with the Florida Citrus Production Advisory Council.

Our operating activities used cash of \$4,413,596 for the nine months ended September 30, 2009 and \$2,331,553 for the nine months ended September 30, 2008. Our working capital deficit was (\$10,273) as of September 30, 2009. Cash used by operations in the nine months ended September 30, 2009 resulted primarily from our net loss from operations of \$4,286,582.

Our investing activities provided an increase in cash of \$18,926 during the nine month period ended September 30, 2009 as compared with a net decrease in cash of \$9,158 for the same period ending September 30, 2008.

Our financing activities for the nine months ended September 30, 2009 provided net cash increase of \$3,953,704. This increase was attributable to the purchase of \$4,000,000, less stock subscription receivable of \$1,000,000, of our common stock by the KFLP; the loan from the KFLP in the amount of \$1,000,000. Additional details of our financing activities are provided below:

**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 unexercised warrants expired 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). In February 2008, amended Warrants, of 4,536,364 were issued upon exercise at the amended exercise price resulting in additional working capital proceeds to us of \$1,996,000. The remaining unexercised August 2007 warrants expired unexercised on August 8, 2008.

**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 May 30, 2013. In connection with, and as a condition to the June 29, 2009 financing transaction described below, the purchasers, including George Hawes our largest shareholder prior to this transaction, under that certain securities purchase agreement dated June 12, 2008, (the “Hawes Agreement”) entered into waiver and release agreements with us. In addition, such individuals waived and relinquished any special rights they possessed pursuant to agreements with the Company, including, but not limited to, (i) rights of first refusal (ii) antidilution regarding future equity sales and (iii) covenants regarding secured lending. In connection with such waivers and releases, warrants to acquire 3,220,000 shares of our common stock at an exercise price of \$1.30 per share that were previously issued under the Hawes Agreement were subject to the right of exchange for new replacement warrants to acquire the same number of shares under the same terms except for a change in the exercise price from \$1.30 to \$0.75. We intend to use the proceeds from the exercise of the warrants, if any, for working capital and general corporate purposes.

**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. We did not draw on this line and on January 21, 2009, this line of credit was terminated by us.

### Short Term Notes Payable

In March 2009, the Company entered into a short term note payable for \$53,087 with an interest rate of 5.75% to finance product liability insurance. This note matures on January 10, 2010. At September 30, 2009 the balance due was \$15,926.

On April 15, 2009 we entered into a loan agreement with an accredited investor for a short term note in the amount of \$100,000. On August 21, 2009 we paid the short term note and outstanding accrued interest in full. The note included an interest rate of 15% per annum and its maturity date was April 15, 2011. In connection with this borrowing we also issued warrants to acquire 100,000 shares of our common stock at an exercise price of \$.50 per share and such warrants are exercisable for five years.

On August 6, 2009 the Company entered into a short term note payable for \$70,023 with an interest rate of 5.75% to finance directors and officers liability insurance. This note matures on May 24, 2010. At September 30, 2009 the balance due was \$56,019.

### **Other Financings**

On May 4, 2009 and June 10, 2009, we borrowed \$32,556 and \$13,100, respectively, from Dr. Jeffery Hillman, our founder, Chief Science Officer and director. These borrowings were to be repaid upon demand by Dr. Hillman, were unsecured and did not bear interest. The proceeds from these borrowings were used to purchase inventory for our Consumer Health Care products division. On June 29, 2009 the aggregate amount of these obligations of \$45,656 were repaid by us in full through the issuance of 456,564 shares of our common stock at a price of \$.10 per share, which was the closing price of our common stock on June 29, 2009.

### **Grants**

On February 15, 2008, we were awarded a two year NSF SBIR Phase II grant to advance development of our small peptide antibiotic synthesis program using the Company's proprietary DPOLT<sup>™</sup>. This federal grant supports 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 \$425,000 of these restricted funds during the last two years.

On September 1, 2009 we received a grant funding from the University of Florida under the prime grant with the Florida Citrus Production Advisory Council in the amount of \$124,570. The purpose of the University of Florida grant is to identify disease-specific proteins expressed during citrus greening using our proprietary PCMAT technology.

**Private Placement, June 2009** – On June 29, 2009, we successfully entered into and consummated a private placement of equity and debt financing pursuant to a Securities Purchase Agreement with an accredited investor. Pursuant to the terms of the Securities Purchase Agreement the Company issued 50,000,000 shares of its Common Stock to the Koski Family Limited Partnership ("KFLP") and issued warrants to the KFLP to acquire 1,000,000 shares of Company common stock at an exercise price of \$0.10 per share in exchange for \$4,000,000, the payment of which consisted of the following: \$1,500,000 in cash at closing and \$2,500,000 pursuant to a non-interest bearing promissory note providing for five consecutive monthly installment payments of \$500,000 commencing July 31, 2009 and the KFLP provided a secured loan of \$1,000,000 to the Company. The loan is secured by substantially all of the Company's assets (excluding receivables) and bears interest at the rate of Prime plus 4.0% which is payable quarterly. The principal of the loan is due in five years. The warrants expire in five years and are immediately exercisable.

Immediately following the closing of the aforementioned June 29, 2009 financing transaction, our Chief Executive Officer Mr. Hirsch was awarded a bonus of \$100,000 which was paid in 1,000,000 shares of our common stock at a price per share of \$0.10. In addition, we issued 250,000 shares of our common stock to our newly appointed Chief Financial Officer for deferred compensation we owed to him and we issued 343,750 shares of our common stock to another employee for deferred compensation we owed to him.

As of September 30, 2009, included in our accounts payable for the period were amounts that we owed to (i) our Chief Science Officer for compensation incurred that we were not able to pay and (ii) former independent directors for prior meeting fees. The deferred aggregate amount owed to our Chief Science Officer and former directors as of September 30, 2009 was \$60,250 and consisted of \$26,250 and \$34,000, respectively. The deferred amounts are expected to be settled by us in future periods. The deferrals of payments to our officer and former directors did not reduce our expenses, but served to preserve our limited cash resources at this time to the extent necessary to maintain our operations.

Our business is based on commercializing entirely new and unique technologies, and our current business plan contains a variety of assumptions and expectations that are subject to uncertainty, including assumptions and expectations about manufacturing capabilities, clinical testing cost and pricing, 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 \$24,279,117 as of September 30, 2009. The net loss from operations for the first nine months of 2009 was \$4,286,582. Cash used in operations for the nine months ended September 30, 2009 was \$4,413,596. As of September 30, 2009, our principal source of liquidity was \$724,967 of cash and cash equivalents and \$1,000,000 in stock subscriptions receivable from the KFLP. These 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 to our commercialization efforts, clinical testing expenditures, as well as conducting basic research. These factors place a significant strain on our limited financial resources and adversely affect our ability to continue as a going concern. Our ultimate success will likely depend on our ability to continue to raise capital for our operations.

Our capital requirements for the remainder of 2009 will depend on numerous factors, including the initial 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 revenue and cash flow from our Consumer Healthcare products division and our ability to raise additional capital including through possible 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.

While we continue to focus on our products and technologies, we may not have sufficient capital resources to market our products and complete the development of our technologies. We had a working capital deficit at September 30, 2009 of (\$10,273). While we believe our currently available cash and cash equivalents of \$1,724,967 (which includes the stock subscription receivable from KFLP of \$1,000,000) is sufficient to enable us to continue to operate during the remainder of 2009, we do not have sufficient capital to operate beyond that time. During this time, if additional capital is not raised, we would need to significantly adjust our current plan of operations until we are able to acquire additional funding. In addition, we expect to continue to explore strategic alternatives that may be available to us and our technologies.

#### **ITEM 4T. CONTROLS AND PROCEDURES**

##### **Evaluation of Disclosure Controls and Procedures**

Management's evaluation of the effectiveness of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act was performed under the supervision and with the participation of our senior management, including our Chief Executive Officer and Chief Financial Officer. The purpose of disclosure controls and procedures is to ensure that information required to be disclosed in the reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Principal Financial Officer, to allow timely decisions regarding required disclosures.

As previously disclosed under Item 4T, *Controls and Procedures*, in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, management concluded that the Company's internal control over financial reporting was not effective because of the existence of material weaknesses in internal control over financial reporting. Based on those material weaknesses, our Chief Executive Officer and Principal Financial Officer have concluded that, as of the quarter ended September 30, 2009, disclosure controls and procedures were not effective. Nevertheless, based on a number of factors, including the performance of additional procedures by management designed to ensure the reliability of our financial reporting, management believes that the financial statements in this Quarterly Report on Form 10-Q fairly present, in all material respects, our financial position, results of operations, and cash flows for the periods presented in conformity with GAAP.

For the period referenced above, the matters involving internal controls and procedures that our management identified and considered to be material weaknesses were: (1) lack of a functioning audit committee due to a lack of a majority of independent members and a lack of outside directors on our board of directors, resulting in ineffective oversight in the establishment and monitoring of required internal controls and procedures; (2) inadequate staffing and supervision that could lead to the untimely identification and resolution of accounting and disclosure matters and failure to perform timely and effective reviews, (3) limited documentation of our system of internal control, (4) insufficient personnel to employ segregation of duties; (5) lack of formal written policies and procedures for accounting and financial reporting with respect to the requirements and application of U.S. GAAP and SEC disclosure requirements and related documentation; (6) deficiencies in our material technology systems and (7) ineffective controls over period end financial disclosure and reporting processes. In addition, our corporate governance activities and processes are not always formally documented or adequately communicated. Specifically, decisions made by the board to be carried out by management should be documented and communicated on a timely basis to reduce the likelihood of any misunderstandings regarding key decisions affecting our operations and management. These deficiencies and weaknesses were largely attributable to the significant lack of available financial resources and corresponding personnel reductions experienced by us during the quarter ended September 30, 2009.

### **Management's Remediation Initiatives**

Although management has not fully remediated the material weaknesses mentioned above, management believes progress has been made during the quarter ending September 30, 2009. We engaged a consulting firm specializing in Sarbanes-Oxley Section 404 compliance to assist us in the implementation of internal controls for financial reporting and disclosure and our remediation efforts. During the quarter the consulting firm completed an initial entity level control evaluation (ELC), control documentation and gap analysis for financial close and reporting. Following such evaluation management prepared a remediation plan to be implemented during the coming months. Management also expects to review various facets of our information processing system, such as cash disbursements, sales and billing, cash receipts and other procedures. We continue to evaluate and address these weaknesses to ensure adherence to our policies, completeness of reporting, segregation of incompatible duties and compliance with generally accepted accounting principles; and we intend to continue to monitor and evaluate these and other factors affecting our internal controls as our available liquidity permits. Until such time, our internal controls over financial reporting may be subject to additional material weaknesses and deficiencies that we have not yet identified. Management is responsible for and is committed to achieving and maintaining a strong control environment, high ethical standards, and financial reporting integrity. This commitment continues to be communicated to and reinforced with our employees.

In an effort to remediate the identified material weaknesses and other deficiencies and enhance our internal controls, we plan to initiate other measures as sufficient funds become available to us. For example, we expect to increase our personnel resources and technical accounting expertise within the accounting function and to create a position to segregate duties consistent with control objectives. In addition, we also plan to appoint one or more outside directors to our board of directors who shall be appointed to an audit committee resulting in a fully functioning audit committee who will undertake the oversight in the establishment and monitoring of required internal controls and procedures such as reviewing and approving estimates and assumptions made by management as funds become available to us. Management believes that the appointment of one or more outside directors, who shall be appointed to a fully functioning audit committee, will remedy the lack of a functioning independent audit committee and a lack of outside directors on our Board.

We anticipate that these initiatives will take time to fully implement following the period of insufficient financial resources we experienced. While we received additional funding on June 29, 2009, we still require funding and our existing capital resources may not be sufficient to address our operational needs or to fully address the weaknesses we have identified. We cannot guarantee that any measures we take will remediate the material weaknesses that we have identified, or that any additional material weaknesses will not arise in the future. In addition, our size prevents us from being able to employ sufficient resources to enable us to have adequate segregation of duties within our internal control system. Management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Because of the inherent limitations of internal control, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

#### **Changes in Internal Controls Over Financial Reporting**

Except as indicated in the preceding paragraphs about management's evaluation of disclosure controls and procedures and internal controls, our management, with the participation of our chief executive officer and chief financial officer, has concluded there were no other significant changes in our internal controls over financial reporting that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### **PART II – OTHER INFORMATION**

#### **ITEM 1. LEGAL PROCEEDINGS**

We are not a party to any pending legal proceeding that is not in the ordinary course of business or otherwise material to our financial condition or business.

#### **ITEM 1A. RISK FACTORS.**

In addition to the other information set forth in this Form 10-Q, you should carefully consider the factors discussed in Part I, Item 1A, subsection "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2008 which could materially affect our business, financial condition or future results of operations. The risks described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008 are not the only risks that we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition and future results of operations. Other than as set forth below, there have been no material changes from the risk factors previously disclosed in Item 1A, subsection "Risk Factors" to Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2008.

You should carefully consider the risks described below 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 modifies or replaces such statement. All of these risks may impair our business operations. The forward-looking statements in this Form 10-Q 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.

## Risks Related to Our Business

***We have a limited operating history with significant losses and expect to continue to experience losses for the foreseeable future and our independent auditors have expressed doubt about our ability to continue as a going concern.***

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. Since our organization, we have incurred operating losses and negative cash flow from operating activities as a result of minimal sales coupled with our significant clinical development, research and development, general and administrative, sales and marketing and business development expenses. Furthermore, our cash burn rate and expenses have recently increased significantly due to our aggressive commercialization, marketing and international initiatives. We expect to incur losses for at least the next several quarters as we expand our sales and marketing capabilities, make use of the sales and marketing capabilities of third parties and continue our clinical trials and research and development activities. Losses have totaled approximately:

\$4,286,582 for the nine months ended September 30, 2009

\$6,021,742 for the year ended December 31, 2008

\$2,311,712 for the year ended December 31, 2007

\$2,935,719 for the year ended December 31, 2006

These losses, among other things, have had and will continue to have an adverse effect on our working capital, total assets and stockholders' deficit. In light of our recurring losses, accumulated deficit and cash flow difficulties, the report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2008 contains an explanatory paragraph raising substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that may be necessary in the event we are unable to continue as a going concern.

We have experienced losses from operations during the last three years and have an accumulated deficit of \$24,279,117 as of September 30, 2009 and \$19,992,535 as of December 31, 2008. We have an operating cash flow deficit of \$4,413,596 for the nine months ended September 30, 2009 and \$3,835,190 for the year ended December 31, 2008 and we sustained operating cash flow deficits of \$1,913,760 and \$2,224,538 in 2007 and 2006, respectively. Our accounts payable and accrued expenses have also increased due to operational changes instituted in connection with the launch of our consumer products. At September 30, 2009, December 31, 2008 and December 31, 2007, we had working capital (deficit) of approximately (\$10,273), (\$500,672) and \$260,534, respectively.

The Company's principal source of liquidity at September 30, 2009 was \$1,724,967 which includes \$724,967 in cash and cash equivalents and \$1,000,000 in stock subscriptions receivable. The Company currently has sufficient capital to operate for the remainder of 2009.

***We continue to require additional financing to operate beyond 2009.***

We do not have sufficient capital to sustain our operations beyond 2009 and we require additional financing. If we are not able to raise additional capital, among other things, we could:

- be forced to reorganize under the protection of the Federal Bankruptcy Laws;
- need to scale back or cease our marketing and development efforts;
- be forced to cease operations;
- be unable to pursue further development of our technologies;
- be forced to sell off our technologies prior to maximizing their potential value;
- be unable to aggressively market our products;
- be unable to pursue patenting some of our technologies and development of our technologies and products;
- have to lay-off personnel;
- be unable to continue to make public filings; and
- have our licenses for our SMaRT™ Replacement Therapy technology and MU 1140 technology could be terminated.

There can be no assurance that we will be able to raise additional capital and any of these events would significantly harm our business.

***The Koski Family Limited Partnership (“KFLP”) has a controlling interest in our outstanding shares of common stock.***

The KFLP own approximately 55% of our outstanding shares of common stock. Our directors, officers and principal (greater than 5%) security holders, taken as a group, together with their affiliates, beneficially own, in the aggregate, approximately 74% of our outstanding shares of \$.001 par value common stock. Certain principal security holders are our directors or executive officers. As a result of such ownership, these security holders may be able to exert significant influence, or even control, matters requiring approval by our security holders, including the election of directors. In addition, certain provisions of Florida law could have the effect of making it more difficult or more expensive for a third party to acquire, or of discouraging a third party from attempting to acquire, control of us.

***We have pledged substantially all of our assets as collateral to secure our indebtedness to the Koski Family Limited Partnership which may limit our ability to incur additional indebtedness or to raise additional capital, and if we fail to meet our payment or other obligations under this debt, the KFLP could foreclose on, and acquire control of, substantially all of our assets.***

We have pledged substantially all our assets as security for borrowings under our promissory note to the Koski Family Limited Partnership. Since substantially all of our assets are used to secure this debt obligation, we have a limited amount of collateral that is available for future secured debt or credit support. As a result, we may be limited in our ability to incur additional debt or equity financings. In addition, if we fail to comply with the terms of our promissory note the KFLP could declare all funds borrowed thereunder to be immediately due and payable. If we are unable to repay the amount owed the KFLP could foreclose on, and acquire control of, substantially all our assets that serve as collateral. We cannot provide any assurances that we will be able to generate sufficient cash from our operations or any financing efforts to repay the promissory note.

***Our business may be adversely affected by the current economic recession.***

The domestic and international economies are experiencing a significant recession. This recession has been magnified by the tightening of the credit markets. The domestic and international markets may remain depressed for an undeterminable period of time. A prolonged recession could have a material adverse effect on the Company's revenues, profits and its ability to obtain additional financing if sales revenue is insufficient to sustain our operations as needed. In such event, we could be forced to limit our marketing and development efforts and significantly curtail or suspend our operations, including laying-off employees, recording asset impairment write-downs and other measures. We must generate significant revenues to achieve and maintain profitability.

***We must spend at least \$1 million annually on development of our MU 1140™ and SMaRT™ Replacement Therapy technologies and \$100,000 annually as minimum royalties under our license agreements with the University of Florida Research Foundation, Inc. We must also comply with certain other conditions of our licenses. If we do not, our licenses to these and other technologies may be terminated, and we may have to cease operations.***

We hold our MU 1140™ and SMaRT™ Replacement Therapy technologies under licenses from the University of Florida Research Foundation, Inc. Under the terms of the licenses, we must spend at least \$1 million per year on development of those technologies before the first commercial sale of products derived from those technologies. In addition, we must pay \$25,000 per quarter as minimum royalties to the University of Florida Research Foundation, Inc. under our license agreements. The University of Florida Research Foundation, Inc. may terminate our licenses in respect of our MU 1140™ and our SMaRT™ Replacement Therapy technology and technology if we breach our obligations to timely pay monies to it, submit development reports to it or commit any other breach of the covenants contained in the license agreements. There is no assurance that we will be able to comply with these conditions. If our license is terminated, our investment in development of our SMaRT™ Replacement Therapy™ and MU 1140™ technologies will become valueless and we may have to cease operations.

Until commercial sales of any products developed from these licensed technologies take place, we will not be earning revenues from the sale of products derived from them and will, therefore, have to raise the money we must spend on development of our technologies by other means, such as commercialization and sale of our consumer products, or the sale of our common stock. There is no assurance we will achieve a sufficient level of sales to provide such funding or be able to raise the financing necessary to meet our obligations under our licenses. If we cannot, we may lose our licenses to these technologies and have to cease operations.



***If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud which could subject us to regulatory sanctions, harm our business and operating results and cause the trading price of our stock to decline.***

Effective internal controls required under Section 404 of the Sarbanes-Oxley Act of 2002 are necessary for us to provide reliable financial reports and effectively prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our business, reputation and operating results could be harmed. We have discovered, and may in the future discover, areas of our internal controls that need improvement. For example, “material weaknesses” were identified in our quarter ended June 30, 2009 which means that there was “a significant deficiency, or a combination of significant deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected.” During this period, we were under significant operational stress due to a lack of liquidity and much of our staff was terminated. During this period and until we can complete our remediation efforts including the re-staffing and training of our accounting personnel, we have a higher risk of deficiencies in our financial reporting. We cannot be certain that the measures we have taken or intend to take will ensure that we maintain adequate controls over our financial processes and reporting in the future. Any failure to implement required new or improved controls or difficulties encountered in their implementation could subject us to regulatory sanctions, harm our business and operating results or cause us to fail to meet our reporting obligations. Inferior internal controls could also harm our reputation and cause investors to lose confidence in our reported financial information, which could have a negative impact on the trading price of our stock.

### **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 need for and availability of working capital, (b) our 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 SALE OF EQUITY SECURITIES AND USE OF PROCEEDS**

- (a) 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 16, 2009 we issued 500,000 shares of our common stock, par value \$.001 per share, to Media4Equity LLC (“M4E”). The restricted shares were issued to M4E pursuant to the terms of an agreement we entered into with M4E effective September 3, 2009, whereby M4E will provide national media exposure consulting services to us relating to the placement of print and radio features. The shares have a fair market value of \$115,000 based on a price of \$0.23 per share. This amount is included in selling, general and administrative expenses in the accompanying statements of operations. In addition to the issuance of common stock the agreement with M4E requires us to make monthly payments to M4E of \$10,000 over the three year term of the agreement, subject to certain termination rights.

On September 14, 2009 we issued a warrant to Strategic Growth International, Inc. (“SGI”) to acquire 250,000 shares of our common stock at \$0.30 per share. The warrant was issued in connection with an agreement with SGI to provide investor relations services to us.

The warrant is currently exercisable and has a three year term. The warrant is substantially similar in form to that of the form of the warrant granted by us to KFLP in connection with our June 29, 2009 financing transaction.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

Incorporated by reference to Exhibits filed after signature page.

**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 13 day of November, 2009.

**ORAGENICS, INC.**

BY: /s/ David B. Hirsch

David B. Hirsch, President and Chief Executive Officer

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## EXHIBIT INDEX

### Incorporated by Reference

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Form</u>	<u>File No</u>	<u>Exhibit</u>	<u>Filing Date</u>	<u>Filed Herewith</u>
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

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## 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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 13, 2009

/s/ David B. Hirsch

David B. Hirsch,  
President and Chief Executive Officer

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## CERTIFICATION

I, Brian J. Bohunicky, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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 13, 2009

/s/ Brian J. Bohunicky  
Brian J. Bohunicky,  
Chief Financial Officer

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**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, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David B. Hirsch, 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 13 day of November, 2009.

/s/ David B. Hirsch  
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David B. Hirsch  
Chief Executive Officer

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**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, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brian J. Bohunicky, 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 13 day of November, 2009.

/s/ Brian J. Bohunicky

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Brian J. Bohunicky  
Chief Financial Officer

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