

**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, 2010.

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.)

**3000 Bayport Drive, Suite 685  
Tampa, Florida 33607**

(Address of principal executive offices)

**813-286-7900**

(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 1, 2010, there were 5,663,076 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>2010</u>	<u>December 31,</u> <u>2009</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 505,215	\$ 301,592
Restricted cash	555,147	2,450,000
Accounts receivables, net	211,842	162,813
Inventory	373,421	132,112
Prepaid offering expense	459,030	—
Prepaid expenses and other current assets	<u>308,758</u>	<u>80,839</u>
Total current assets	2,413,413	3,127,356
Property and equipment, net	<u>227,164</u>	<u>75,480</u>
Total assets	<u>\$ 2,640,577</u>	<u>\$ 3,202,836</u>
<b>Liabilities and Shareholders' Equity (Deficit)</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,290,796	\$ 478,111
Short term notes payable	158,768	35,012
Revolving payable to shareholder	1,000,000	—
Deferred revenue	<u>15,463</u>	<u>50,086</u>
Total current liabilities	2,465,027	563,209
Shareholders' equity (deficit):		
Preferred stock, no par value; 20,000,000 shares authorized; none issued and outstanding	—	—
Common stock, \$0.001 par value; 15,000,000 shares authorized; 5,663,076 and 5,304,157 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively.	5,663	5,304
Additional paid-in capital	31,314,419	28,146,206
Accumulated deficit	<u>(31,144,532)</u>	<u>(25,511,883)</u>
Total shareholders' equity (deficit)	<u>175,550</u>	<u>2,639,627</u>
Total liabilities and shareholders' equity (deficit)	<u>\$ 2,640,577</u>	<u>\$ 3,202,836</u>

*See accompanying notes.*

[Table of Contents](#)**Oragenics, Inc.****Statements of Operations  
(Unaudited)**

	Three months ended September 30		Nine months ended September 30	
	2010	2009	2010	2009
Net revenue	\$ 364,574	\$ 199,675	\$ 1,010,753	\$ 365,842
Cost of goods sold	147,257	65,461	473,578	100,844
Operating expenses:				
Research and development	463,410	427,541	1,373,248	1,407,516
Selling, general and administrative	1,624,524	1,165,812	4,792,150	3,883,984
Total operating expenses	<u>2,087,934</u>	<u>1,593,353</u>	<u>6,165,398</u>	<u>5,291,500</u>
Loss from operations	(1,870,617)	(1,459,139)	(5,628,223)	(5,026,502)
Other income (expense):				
Interest income	600	275	3,135	796
Interest expense	(4,107)	(24,412)	(4,992)	(25,915)
Gain on sale of property and equipment	—	—	—	11,274
Gain on extinguishment of payables	—	46,268	—	753,942
Local business tax	(1,104)	—	(2,569)	(177)
Total other income (expense), net	<u>(4,611)</u>	<u>22,131</u>	<u>(4,427)</u>	<u>739,920</u>
Loss before income taxes	<u>(1,875,228)</u>	<u>(1,437,008)</u>	<u>(5,632,650)</u>	<u>(4,286,582)</u>
Net loss	<u>\$(1,875,228)</u>	<u>\$(1,437,008)</u>	<u>\$(5,632,650)</u>	<u>\$(4,286,582)</u>
Basic and diluted net loss per share	<u>\$ (0.34)</u>	<u>\$ (0.32)</u>	<u>\$ (1.03)</u>	<u>\$ (1.53)</u>
Shares used to compute basic and diluted net loss per share	<u>5,584,974</u>	<u>4,521,956</u>	<u>5,460,353</u>	<u>2,803,591</u>

See accompanying notes.

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**Oragenics, Inc.**  
**Statements of Cash Flows**  
**(Unaudited)**

	Nine months ended September 30	
	2010	2009
<b>Cash flows from operating activities:</b>		
Net loss	\$(5,632,650)	\$(4,286,582)
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	99,000	115,000
Non-cash settlement of amounts owed to employees	—	59,376
Depreciation and amortization	27,697	198,607
Stock-based compensation expense	569,572	250,690
Gain on extinguishment of payables	—	(753,942)
Gain on sale of property and equipment	—	(11,274)
Changes in operating assets and liabilities:		
Accounts receivable, net	(49,029)	(3,590)
Inventory	(241,309)	(102,304)
Prepaid expenses and other current assets	(227,919)	95,963
Accounts payable and accrued expenses	812,685	(102,474)
Deferred revenue	(34,623)	110,267
Deferred compensation	—	(83,333)
Net cash used in operating activities	(4,676,576)	(4,413,596)
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(179,381)	(9,074)
Proceeds from sale of property and equipment	—	28,000
Net cash (used in) provided by investing activities	(179,381)	18,926
<b>Cash flows from financing activities:</b>		
Borrowings under short term notes payable	216,298	132,556
Borrowings under long term notes payable	—	1,000,000
Borrowings under note payable from shareholder	1,000,000	—
Borrowings under revolving note payable to shareholder	1,000,000	—
Payments on short term notes payable	(92,542)	(178,852)
Net proceeds from issuance of common stock	1,500,000	3,000,000
Prepaid offering expenses	(459,030)	—
Restricted cash released from common stock proceeds	1,894,853	—
Net cash provided by financing activities	5,059,579	3,953,704
Net (decrease) increase in cash and cash equivalents	203,623	(440,966)
Cash and cash equivalents at beginning of the period	301,592	1,165,933
Cash and cash equivalents at end of the period	<u>\$ 505,215</u>	<u>\$ 724,967</u>
<b>Supplemental disclosure of cash flow information</b>		
Interest paid	<u>\$ 19,994</u>	<u>\$ 8,042</u>
Non-cash investing and financing activities:		
Stock subscription receivable	<u>\$ —</u>	<u>\$ 1,000,000</u>
Issuance of common stock to employees as settlement of amounts owed	<u>\$ —</u>	<u>\$ 205,032</u>
Borrowings under short term notes payable for prepaid expense	<u>\$ —</u>	<u>\$ 123,112</u>
Common stock issued in exchange for cancellation of note payable to shareholder	<u>\$ 1,000,000</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, 2010 and December 31, 2009 and for the three and nine months ended September 30, 2010 and 2009 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, 2010 are not necessarily indicative of the results that may be expected for the year ended December 31, 2010 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, 2009, which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2010. 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.

On September 24, 2010, the amendment to our articles of incorporation was filed with the Florida Department of State became effective with respect to a 20 – to – 1 reverse stock split of our authorized shares of common stock. As a result of the reverse stock split, every 20 shares of the Company’s common stock were combined into one share of common stock. All common stock equity transactions have been adjusted to reflect the reverse stock split for all periods presented.

**Adoption of New Accounting Standard**

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.

**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 the 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.

The Company records allowances for discounts and product returns at the time of sales as a reduction of revenue as such allowances can be reasonably estimated based on historical experience or known trends. Product returns are

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limited to specific mass retail customers for expiration of shelf life or unsold product over a period of time.

### 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. As of September 30, 2010, we had \$64,176 in consignment inventory with a mass retailer which will be reduced as shipments are made.

### Prepaid Offering Expense

The Company recorded prepaid offering expense of \$459,030 during the three months ending September 30, 2010. Prepaid offering expense is attributable to the expenses associated with our current capital raise efforts. We expect to incur additional expenses associated with our capital raise efforts in the future. We incurred \$150,000 of additional expense from October 1, 2010 through the date of the filing associated with our ongoing efforts to raise capital. If the offering is successfully completed resulting in the sale of common stock, prepaid offering expenses will be treated as a reduction in proceeds and classified as equity. If the capital raising efforts for which these expenses relate is terminated or abandoned by us, the prepaid expenses will be expensed in the period in which such determination is made.

## 2. Net Loss Per Share

During all periods presented, the Company had securities outstanding that could potentially dilute basic earnings per share in the future, but were excluded from the computation of diluted net loss per share, as their effect would have been antidilutive. Because the Company reported a net loss for all periods presented, shares associated with the stock options and warrants are not included because they are antidilutive. Basic and diluted net loss per share amounts are the same for the periods presented. Net loss per share is computed using the weighted average number of shares of common stock outstanding.

## 3. Income Taxes

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

In July 2006, the FASB issued guidance which clarifies accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with GAAP and prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under GAAP, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, GAAP provides guidance on derecognition, classification, interest and penalties, accounting for interim periods, disclosure and transition.

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 2006.

## 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:

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*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, 2010. 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, 2010.

### 5. Stock Options Expense During the nine months ended September 30, 2010

During the nine months ended September 30, 2010, the Company issued 27,326 stock options of which 13,000 vested immediately. From January 1, 2010 to the date of this filing 13,000 stock options previously granted have vested and 12,178 have been forfeited. Stock option compensation expense of \$569,572 was recorded for the nine months ended September 30, 2010 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 nine months ended September 30, 2010

In January 2010, we completed the closing of a \$3,000,000 million private placement of common stock pursuant to a Common Stock Purchase Agreement with accredited investors. The Company issued an additional 100,000 shares of its Common Stock at a price of \$5.00 per share to the investors for \$500,000, the payment of which consisted of \$500,000 in cash at closing. Half of the total investment, or \$250,000, was made by the Koski Family Limited Partnership.

In June 2010, we issued 6,000 shares to Athorn Clark Partners (“Athorn”) at a price per share of \$12.50 (based on the value of the services required to be provided by Athorn) in connection with an agreement for Athorn to provide media related services to us.

On July 5, 2010, we entered into a common stock purchase agreement (the “July 2010 Financing Transaction”) with the Koski Family Limited Partnership (KFLP). At the closing of the financing transaction on July 30, 2010 we issued 250,000 shares of our common stock to the KFLP at a price of \$8.00 per share. The \$2,000,000 aggregate consideration paid by the KFLP consisted of (i) \$1,000,000 cash and (ii) the exchange and cancellation of the \$1,000,000 unsecured promissory note (the “May 2010 Note”) issued to the KFLP on May 24, 2010. Accrued interest on the May 2010 Note through closing was waived by the KFLP.

On July 14, 2010, we issued 3,000 shares to Mr. David McKeon (d/b/a Game On Consulting) at a price per share of \$8.00 as part to a consulting agreement to provide services to the Company. The share price is based on value of the company’s common stock at the time the agreement was signed.

### 7. Short Term Notes Payable

On March 17, 2010, we entered into a short term note payable for \$50,637 with an interest rate of 5.75% to finance our product liability insurance. Payments on this note are made evenly based on a straight line amortization over a ten-month period with the final payment due January 10, 2011. At September 30, 2010 the outstanding balance due was \$15,191.

On July 9, 2010, we entered into a non-interest bearing short-term note payable for \$22,188 to finance a portion of our new enterprise resource planning system. Payments on this note began July 9, 2010 and are made quarterly with the final payment due on April 1, 2011.



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On July 20, 2010, we entered into a short-term note payable for \$65,529 with an interest rate of 5.75% to finance product liability insurance. Payments on this note begin on August 24, 2010 and are made evenly based upon a straight line amortization over ten-month period with the final payment due on July 24, 2011.

On July 31, 2010, we entered into a short-term note payable for \$85,185 bearing interest at 7.5% to finance a portion our new enterprise resource planning system. Principal and interest payments on this note begin August 31, 2010 and are made evenly based on a straight line amortization over a 17-month period with the final payment due on December 31, 2011.

### 8. Note Payable to Shareholder

On July 30, 2010, The Company entered into a revolving credit facility agreement with the KFLP for maximum borrowing of \$2,000,000 at LIBOR plus 6.0%, subject to certain conditions precedent, including compliance with the Credit Facility. The term of the Credit Facility is for twelve months commencing August 1, 2010. On September 13, 2010, the Company drew down on the Credit Facility in the amount of one million dollars \$1,000,000 and executed a Revolving Unsecured Promissory Note (the "September Promissory Note") for such amount in favor of the KFLP. In addition, on November 8, 2010 the Company drew down on the remaining \$1.0 million of available funds under the Credit Facility and executed another Revolving Unsecured Promissory Note (the "November Promissory Note"). The September Promissory Note and November Promissory Note each mature on July 30, 2011.

### 9. Outstanding Warrants and Stock Options

As of the date of this filing there are approximately 306,388 warrants outstanding and there are approximately 398,114 outstanding stock options that have been granted that have not been forfeited. The total number of outstanding warrants and unexercised stock options is 704,502. If all warrants and stock options were exercised, the total number of outstanding shares would be approximately 6,367,579.

### 10. Subsequent Events

The Company has evaluated subsequent events through the date these financial statements were available to be issued, November 12, 2010. With the exceptions of the matters discussed below, there were no material subsequent events that required recognition or additional disclosure in these financial statements.

On November 1, 2010, the Company received notification that it will receive federal grant funding for three of its therapeutic development programs under the Qualifying Therapeutic Discovery Project. The Qualifying Therapeutic Discovery Project, was recently enacted by Congress as part of the Patient Protection and Affordable Care Act of 2010, which was designed to provide grants or tax credits to qualified biotechnology companies that demonstrate the potential to either 1) develop new therapies to treat areas of unmet medical needs; 2) prevent, detect or treat chronic or acute diseases and conditions; 3) reduce long-term health care costs in United States; or 4) significantly advance the goal of curing cancer within the 30 year period beginning on May 21, 2010. The Company applied for funding on three of its programs: Prevention of Tooth Decay using Smart Replacement Therapy, Novel Antibiotics for the Treatment of Healthcare Associated Infections and Rapid and Sensitive Identification of Novel Diagnostic Biomarkers for Cancer and Infectious Diseases. The Company will receive a non-taxable cash grant award totaling \$733,437 under the program. A payment of \$371,219 has been authorized to be made to the Company in November 2010 and the remaining grant award amount of \$362,218 will be authorized for payment to the Company no later than 30 days after the end of the calendar year ending December 31, 2010.

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### **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 biopharmaceutical company focused primarily on oral health products and novel antibiotics. Within oral health, we are developing our pharmaceutical product candidate, SMaRT Replacement Therapy, and we are also commercializing our oral probiotic blend, ProBiora3. Within antibiotics, we are developing our pharmaceutical product candidate, MU1140-S, and we intend to use our patented, novel organic chemistry platform to create additional antibiotics for therapeutic use.

Our SMaRT Replacement Therapy product candidate is designed to be a painless, one-time, five-minute topical treatment applied to the teeth that has the potential to offer lifelong protection against dental caries, or tooth decay. Our SMaRT Replacement Therapy is based on the creation of a genetically modified strain of bacteria that colonizes in the oral cavity and replaces native bacteria that cause tooth decay. We expect to commence a second Phase 1 clinical trial for SMaRT Replacement Therapy which we expect to conclude in 2011. We have also developed and are commercializing a variety of products that contain the active ingredient ProBiora3, a patent pending blend of oral probiotics that promote fresher breath, whiter teeth and support overall oral health. We have conducted extensive scientific studies on ProBiora3 in order to market our products under self-affirmed Generally Recognized As Safe status, or GRAS. We sell our ProBiora3 products through multiple distribution channels and our customers include Walgreens, Rite Aid, and Garden of Life, among others.

While developing SMaRT Replacement Therapy, members of our scientific team discovered that the SMaRT bacterial strain produces MU1140, a molecule belonging to the novel class of antibiotics known as lantibiotics. MU1140 has proven active preclinically against Gram positive bacteria responsible for a number of HAIs. We are in the process of scaling up production of our synthetic form of MU1140, or MU1140-S, and expect to commence preclinical testing and to file an Investigational New Drug, or IND, application with the FDA in 2011. The key technology behind the production of MU1140-S is our Differentially Protected Orthogonal Lanthionine Technology platform, or DPOLT, which is a patented, novel organic chemistry platform that we believe will enable the first ever commercial scale, cost-effective production of any of the 50 known lantibiotics. We intend to use DPOLT to create a pipeline of lantibiotics for therapeutic use. Additionally, we are developing non-core technologies that originated from the discoveries of our scientific team, including LPT3-04, which is a weight loss product, and PCMAT, which is a biomarker discovery platform, both of which we believe could provide significant potential opportunities for us.

We were incorporated in November 1996 and commenced operations in 1999. We consummated our initial public offering in June 2003. We have devoted substantially all of our resources to the commercialization of our ProBiora3 products as well as our discovery efforts comprising research and development, clinical trials for our product candidates, protection of our intellectual property and the general and administrative support of these operations. We have generated limited revenues from grants and ProBiora3 product sales through June 30, 2010, and have principally funded our operations through the sale of debt and equity securities, including the exercise of warrants issued in connection with these financing transactions. Prior to 2008 our revenues were derived solely from research grants. Since 2008, our revenues have also included sales of our ProBiora3 products, which we initiated in late 2008. Our net revenues were \$1,010,753 for the nine months ended September 30, 2010 and \$641,285 for the year ended December 31, 2009.

We have never been profitable and, as of September 30, 2010, we had an accumulated deficit of \$31,144,532. We incurred net losses of \$5,632,650 for the nine months ended September 30, 2010 and \$5,519,348 and \$6,021,742 for the years ended December 31, 2009 and 2008, respectively. We expect to incur significant and increasing operating losses for the foreseeable future as we advance our product candidates through preclinical testing and clinical trials to seek regulatory approval and eventual commercialization. The report of our independent registered public accounting firm with respect to our financial statements appearing in our Form 10-K contains an explanatory paragraph stating that our

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operating losses and negative cash flows from operations since inception, and our need to raise additional financing and/or financial support prior to December 31, 2010 in order to continue to fund our operations, raise substantial doubt about our ability to continue as a going concern. Adequate additional funding may not be available to us on acceptable terms, or at all. We expect that research and development expenses will increase along with general and administrative costs, as we grow and operate our business. There can be no assurance that additional capital will be available to us on acceptable terms, if at all.

### **Recent Developments**

On September 24, 2010 the amendment to our articles of incorporation that we filed with the Florida Department of State became effective with respect to a 20-to-1 reverse stock split of our authorized and outstanding shares of common stock.

On July 5, 2010, we entered into a common stock purchase agreement (the “July 2010 Financing Transaction”) with the Koski Family Limited Partnership, or KFLP. At the closing of this financing transaction on July 30, 2010 we issued 250,000 shares of our common stock to the KFLP at a price of \$8.00 per share. The \$2,000,000 aggregate consideration paid by the KFLP consisted of (i) \$1,000,000 cash and (ii) the exchange and cancellation of the outstanding May 2010 Note issued to the KFLP on May 28, 2010. Accrued interest on the May 2010 Note through closing was waived by the KFLP. Concurrent with the July 2010 Financing Transaction and as part thereof, we entered into an unsecured revolving credit agreement (the “Credit Facility”) with the KFLP. Pursuant to the Credit Facility, we are able to borrow up to \$2,000,000 from the KFLP at LIBOR plus 6.0%. The term of the Credit Facility is for 12 months commencing August 1, 2010. On September 13, 2010, the Company drew down on the Credit Facility in the amount of one million dollars \$1,000,000 and executed a Revolving Unsecured Promissory Note (the “September Promissory Note”) for such amount in favor of the KFLP. In addition, on November 8, 2010 the Company drew down on the remaining \$1.0 million of available funds under the Credit Facility and executed another Revolving Unsecured Promissory Note (the “November Promissory Note”). The September Promissory Note and November Promissory Note each mature on July 30, 2011.

We have continued our efforts to broaden the distribution of our ProBiora3 products through the following business development activities:

- American Dental Association: From October 9-12, 2010, we exhibited EvoraPro to dental professionals at their Annual Session and World Marketplace Exhibition.
- Best Supplies: On September 30, 2010, we announced that Teddy’s Pride will be available in Taiwan through a distribution agreement with The Best Supplies LTD, which has 70 pet supply retail shops across Taiwan.
- Rolf C. Hagen, Inc.: On September 23, 2010, we announced the distribution of Teddy’s Pride in Canada through Rolf C. Hagen, one of the largest privately held pet product manufacturers in the world.
- Benelux Cosmetics: On September 21, 2010, we announced that our line of ProBiora3 products will be distributed in Belgium, the Netherlands and Luxembourg through Benelux Cosmetics.
- Vetcom: On September 20, 2010, we announced that Teddy’s Pride will be distributed to veterinarians in Korea through Vetcom Korea, Inc. Vetcom Korea is a leading national distributor of products for the veterinarian industry.
- Fred Meyer: On September 16, 2010, we announced an initial order of EvoraPlus from Fred Meyer, which operates 129 multi-department stores in four western states.
- SuperZoo: From September 14-16, 2010, we introduced Teddy’s Pride to SuperZoo, an annual pet trade show and seminar by the World Pet Association, which was attended by over 9,000 pet professionals from around the world.
- Kroger: On September 14, 2010, we announced the expansion of the retail distribution of EvoraPlus through an initial order from Kroger Co. Kroger is the nation’s largest traditional grocery retailer with approximately 2,500 stores in 31 states. We anticipate that EvoraPlus will be available in select Kroger grocery stores beginning in October 2010.
- Harris Teeter: On September 10, 2010, we announced an initial order of EvoraPlus and EvoraKids from Harris Teeter. Harris Teeter is a food market chain that operates in eight states with 196 stores.

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- GNC: On September 7, 2010, we announced that EvoraPlus will be available in corporate-owned GNC stores nationwide and EvoraKids will be available in its concept stores and on GNC.com. GNC is a leading global specialty retailer of nutritional products with over 7,000 locations.

On November 1, 2010, the Company received notification that it will receive federal grant funding for three of its therapeutic development programs under the Qualifying Therapeutic Discovery Project. The Qualifying Therapeutic Discovery Project, was recently enacted by Congress as part of the Patient Protection and Affordable Care Act of 2010, which was designed to provide grants or tax credits to qualified biotechnology companies that demonstrate the potential to either 1) develop new therapies to treat areas of unmet medical needs; 2) prevent, detect or treat chronic or acute diseases and conditions; 3) reduce long-term health care costs in United States; or 4) significantly advance the goal of curing cancer within the 30 year period beginning on May 21, 2010. The Company applied for funding on three of its programs: Prevention of Tooth Decay using Smart Replacement Therapy, Novel Antibiotics for the Treatment of Healthcare Associated Infections and Rapid and Sensitive Identification of Novel Diagnostic Biomarkers for Cancer and Infectious Diseases. The Company will receive a non-taxable cash grant award totaling \$733,437 under the program. A payment of \$371,219 has been authorized to be made to the Company in November 2010 and the remaining grant award amount of \$362,218 will be authorized for payment to the Company no later than 30 days after the end of the calendar year ending December 31, 2010.

## **Financial Overview**

### ***Net Revenues***

Our revenues prior to 2008 consisted exclusively of grant funding from government agencies under the National Science Foundation's, or NSF, and National Institutes of Health's, or NIH, Small Business Innovation Research, or SBIR, grants. Since the initial launch of our ProBiora3 products in late 2008, our net revenues for the year ended December 31, 2008 also included sales of our ProBiora3 products. Sales of our ProBiora3 products were \$848,181, for the nine months ended September 30, 2010 and \$366,801 and \$8,539 for the years ended December 31, 2009 and 2008, respectively. Because of our efforts to increase the distribution of our ProBiora3 products, we expect net revenues to continue to increase in the near future. However, our success will depend on a number of factors, including our marketing efforts related to our ProBiora3 products.

We expect that our revenues will fluctuate from quarter to quarter as a result of the volume of sales of our products and the amount of license fees, research and development reimbursements, milestone and other payments we may receive upon any license or strategic partnerships we may enter into in the future.

### ***Cost of Goods Sold***

Our cost of goods sold includes the production and manufacture of our ProBiora3 products, as well as shipping and processing expenses and scrap expense. Scrap expense represents product rework charges, inventory adjustments, and damaged inventory. We expect our costs of goods sold to increase as we expand our distribution and sales efforts for our ProBiora3 products.

### ***Research and Development Expenses***

Research and development consists of expenses incurred in connection with the discovery and development of our product candidates. These expenses consist primarily of employee-related expenses, which include salaries and benefits and attending science conferences; expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies; the cost of acquiring and manufacturing clinical trial materials; facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, and depreciation of fixed assets; license fees for and milestone payments related to in-licensed products and technology; stock-based compensation expense; and costs associated with non-clinical activities and regulatory approvals. We expense research and development costs as incurred.

We plan to increase our research and development expenses for the foreseeable future as we seek to advance the development of our SMaRT Replacement Therapy and MU1140-S product candidates, and to further advance our earlier stage research and development projects, such as LPT3-04, our potential weight loss product, and PCMAT, our biomarker discovery platform.

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Prior to January 1, 2009, we did not track our internal research and development costs or our personnel and personnel-related costs on a project-by-project basis, instead, our research and development resources were allocated among all of our programs. Since January 1, 2009, we have tracked development expenses and personnel expense on a project-by-project basis and have allocated common expenses, such as scientific consultants and lab supplies, to each program based on the personnel resources allocated to each program.

Our research and development expenses were \$1,373,248 for the nine months ended September 30, 2010 and \$1,833,746 and \$1,955,488 for the years ended December 31, 2009 and 2008, respectively. Our research and development expenses can be divided into (i) clinical research and development, and (ii) preclinical research and development activities. Clinical research and development costs consist of clinical trials, manufacturing services, regulatory activities and related personnel costs, and other costs such as rent, utilities, depreciation and stock-based compensation. Preclinical research and development costs consist of our research activities, preclinical studies, related personnel costs and laboratory supplies, and other costs such as rent, utilities, depreciation and stock-based compensation. While we are currently focused on advancing each of our product development programs, our future research and development expenses will depend on the clinical success of each product candidate, as well as ongoing assessments of each product candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

We expect our research and development expenses to increase in the future as we continue the advancement of our clinical trials and preclinical product development programs. The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates requires expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenues and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations. Our current product development candidates are not expected to be commercially available before 2011.

### ***Selling, General and Administrative Expenses***

Selling, general and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, business development, marketing, information technology, legal and human resources functions. Other general and administrative expenses include facility costs not otherwise included in research and development expenses, patent filing, prosecution and defense costs and professional fees for legal, consulting, auditing and tax services.

We anticipate that our general and administrative expenses will increase for, among others, the following reasons:

- the sales and marketing of our ProBiora3 products;
- to support our research and development activities, which, subject to available capital, we expect to expand as we continue the development of our product candidates;
- the efforts we undertake from, time to time, to raise additional capital; and
- the increased payroll, expanded infrastructure and higher consulting, legal, accounting and investor relations costs associated with being a public company.

### ***Other Income and (Expense)***

Other income and expense includes gain or loss on sale of assets, local business taxes, and extinguishment of payables as well as interest income and expense. Interest income consists of interest earned on our cash and cash equivalents. The primary objective of our investment policy is capital preservation. Interest expense consists primarily of interest and costs associated with our loans payable.

### ***Income Taxes***

As of December 31, 2009, we had federal and state net operating loss carryforwards and research and development tax credit carryforwards of approximately \$23,125,665 and \$384,276, respectively. Our net operating loss and research and development tax credit carryforwards will expire, if not used, between 2010 and 2029. Our ability to utilize our net operating loss and tax credit carryforwards may be limited in the event a change in ownership, as defined in Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, has occurred or may occur in the future. The private

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placement transaction with the KFLP in June 2009 (the “June 2009 Private Placement”) constituted such an event and our historical loss carryforwards were limited. See “Tax Loss Carryforwards.” In each period since our inception, we have recorded a 100% valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recorded any federal tax benefit in our statements of operations.

### **Critical Accounting Estimates and Policies**

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The preparation of financial statements in accordance with U.S. GAAP 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. The principal areas of estimation reflected in the financial statements are stock-based compensation, valuation of warrants, sales returns and allowances and allowance for doubtful accounts.

### ***Revenue Recognition***

We recognize revenues from the sales of product when title and risk of loss pass to the customer, which is generally when the 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

We record allowances for discounts and product returns at the time of sales as a reduction of revenues as such allowances can be reliably estimated based on historical experience or known trends. Product returns are limited to specific mass retail customers for expiration of shelf life or unsold product over a period of time. We maintain a return policy that allows our customers to return product within a specified period of time prior to and subsequent to the expiration date of the product. Our estimate of the provision for returns is analyzed quarterly and is based upon many factors, including industry data of product return rates, historical experience of actual returns, analysis of the level of inventory in the distribution channel, if any, and reorder rates. If the history or our product returns changes, the reserve will be adjusted. While we believe that the reserves we have established are reasonable and appropriate based upon current facts and circumstances, applying different judgments to the same facts and circumstances would result in the estimated amounts for sales returns and chargebacks to vary. Because our ProBiora3 products have only recently been introduced, we could experience different circumstances in the future and these differences could be material.

### ***Accounts Receivable***

Accounts receivable are recorded at their net realizable value and consist of trade receivables from the sale of product to customers. We analyze accounts receivable on a monthly basis and determine the collectability based on the facts and circumstances relating to each customer. We do not have a history of accounts receivable or write offs, therefore, we estimate our allowance for doubtful accounts based on sales trends and specific review of the creditworthiness of each customer.

### ***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. On a quarterly basis, we analyze our inventory levels and write-down inventory that is expected to expire prior to being sold, inventory that has a cost basis in excess of its expected net realizable value, inventory in excess of expected sales requirements, or inventory that fails to meet commercial sale specifications through a charge to cost of goods sold. Expired inventory is disposed of and the related costs are written off to cost of goods sold. Charges for inventory write-downs are not reversed if we later determine that the product is saleable. Therefore, any such written-down inventory would be sold at significantly higher margin. If actual conditions are less favorable than those projected by management, additional inventory write-downs may be required.

### ***Prepaid Offering Expense***

The Company recorded prepaid offering expense of \$459,030 during the three months ending September 30, 2010. Prepaid offering expense is attributable to the expenses associated with our current capital raise efforts. We expect to incur additional expenses associated with our capital raise efforts in the future. We incurred \$150,000 of additional expense from October 1, 2010 through the date of the filing associated with our ongoing efforts to raise capital. If the

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offering is successfully completed resulting in the sale of common stock, prepaid offering expenses will be treated as a reduction in proceeds and classified as equity. If the capital raising efforts for which these expenses relate is terminated or abandoned by us, the prepaid expenses will be expensed in the period in which such determination is made.

### ***Stock-Based Compensation***

U.S. GAAP requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values as of the grant dates. Stock-based compensation expense is recorded over the requisite service period in which the grantee provides services to us, to the extent the options or warrants do not vest at the grant date and are not subject to forfeiture.

### ***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. Based on our historical operating losses, a valuation allowance has been recognized for all deferred tax assets.

### ***New Accounting Pronouncements***

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 our financial statements.

In October 2009, the FASB issued ASC Update No. 2009-13, Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements ("Update No. 2009-13"). The consensus in Update No. 2009-13 supersedes certain guidance in Topic 605 (formerly EITF Issue No. 00-21, Multiple-Element Arrangements) and requires an entity to allocate arrangement consideration at the inception of an arrangement to all of its deliverables based on their relative selling prices. The consensus eliminates the use of the residual method of allocation and requires the use of the relative-selling-price method in all circumstances in which an entity recognizes revenues for an arrangement with multiple deliverables subject to ASC 605-25. We are required to adopt Update No. 2009-13 as of January 1, 2011 and are in the process of determining the impact, if any. However, we do not believe that the adoption of Update No. 2009-13 will have a material effect on our financial statements.

### ***Results of Operation***

*For the Three Months Ended September 30, 2010 and 2009*

***Net Revenues.*** We generated net revenues of \$364,574 for the three months ended September 30, 2010 compared to \$199,675 in the same period in 2009, an increase of \$164,899. The increase was primarily attributable to an increase in ProBiora3 product sales, offset by increases in returns, allowances, and discounts of \$91,714. The increase in net revenues also included a \$76,794 decrease in grant revenues attributable to an NSF SBIR Phase II grant for the small peptide antibiotic synthesis program using our proprietary DPOLT and the completion of the University of Florida grant to identify disease-specific proteins expressed during citrus greening using our proprietary PCMAT.

***Cost of Goods Sold.*** Cost of goods sold was \$147,257 for the three months ended September 30, 2010 compared to \$65,461 in the same period in 2009, an increase of \$81,796. The increase was attributable to increased sales of our ProBiora3 products. Cost of goods sold includes the production and manufacturing costs of our ProBiora3 products sold

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of \$109,743, shipping and processing expenses of \$36,616, and scrap expense of \$898. Scrap expenses represent product rework charges, inventory adjustments, and damaged inventory.

**Research and Development.** Research and development expenses were \$463,410 for the three months ended September 30, 2010 compared to \$427,541 in the same period in 2009, a increase of \$35,869, or 8.4%. This increase in research and development expenses was primarily due to increases in DPOLT consulting spending.

**Selling, General and Administrative.** Selling, general and administrative expenses were \$1,624,524 for the three months ended September 30, 2010 compared to \$1,165,812 in the same period in 2009, an increase of \$458,712, or 39.4%. This increase was due to increases in salary and fringe costs of \$116,574 as a result of additional staff and increases in compensation of existing personnel, advertising and marketing expenses of \$243,152 Board of Director fees and stock-based compensation expense of \$46,678, and increases in consulting fees \$87,571. The increase in selling, general and administrative expense was offset primarily by reductions in legal and professional support service fee savings of \$46,412.

**Other Income (Expense).** Other income and expense was \$4,611 of other expenses for the three months ended September 30, 2010 compared to \$22,131 of other income in the same period in 2009, an increase of expenses of \$26,742. The increase was primarily attributable to the absence of a \$46,268 gain we recognized in 2009 associated with the extinguishment of payables in connection with the June 2009 Private Placement. In addition, the increase in other income and expense for the period was impacted by a decrease in interest expense of \$20,305, an increase in interest income of \$325, as well as local business tax expenses we incurred during the period of \$1,104.

*For the Nine Months Ended September 30, 2010 and 2009*

**Net Revenues.** We generated net revenues of \$1,010,753 for the nine months ended September 30, 2010 compared to \$365,842 in the same period in 2009, an increase of \$644,911. The increase was primarily attributable to an increase in ProBiora3 product sales, offset by increases in returns, allowances, and discounts of \$112,787. The increase in net revenues also included a \$51,730 decrease in grant revenues attributable to an NSF SBIR Phase II grant for the small peptide antibiotic synthesis program using our proprietary DPOLT and the completion of the University of Florida grant to identify disease-specific proteins expressed during citrus greening using our proprietary PCMAT.

**Cost of Goods Sold.** Cost of goods sold was \$473,578 for the nine months ended September 30, 2010 compared to \$100,844 in the same period in 2009, an increase of \$372,734. The increase was attributable to increased sales of our ProBiora3 products. Cost of goods sold includes the production and manufacturing costs of our ProBiora3 products sold of \$255,593, shipping and processing expenses of \$108,702, and scrap expense of \$109,283. Scrap expenses represent product rework charges, inventory adjustments, and damaged inventory.

**Research and Development.** Research and development expenses were \$1,373,248 for the nine months ended September 30, 2010 compared to \$1,407,516 in the same period in 2009, a decrease of \$34,268, or 2.5%. This decrease in research and development expenses was primarily due to depreciation expense savings stemming from the full depreciation of certain lab equipment.

**Selling, General and Administrative.** Selling, general and administrative expenses were \$4,792,150 for the nine months ended September 30, 2010 compared to \$3,883,984 in the same period in 2009, an increase of \$908,166, or 23.4%. This increase was due to increases in stock-based compensation expense of \$167,756, salary and fringe costs of \$369,959 as a result of additional staff and increases in compensation of existing personnel, advertising and marketing expenses of \$902,950, and Board of Director compensation of \$108,557. The increase in selling, general and administrative expense was offset primarily by reductions in legal and professional support service fee savings of \$414,074, and consultant expenses of \$199,872 associated primarily with reduced investor relations consulting spending.

**Other Income (Expense).** Other income and expense was \$4,427 of expense for the nine months ended September 30, 2010 compared to \$739,920 of income in the same period in 2009, an increase of expenses \$774,347. The increase of expenses was primarily attributable to the absence of a \$753,942 gain we recognized in 2009 associated with the extinguishment of payables in connection with the June 2009 Private Placement, and a \$11,274 gain we realized in 2009 on the sale of assets. In addition, the increase in other income and expense for the period was impacted by a decrease in interest expense of \$20,923, an increase in interest income of \$2,339, as well as local business tax expenses we incurred during the period of \$2,569.

## **Liquidity and Capital Resources**



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Since our inception, we have funded our operations primarily through the sale of equity securities in our initial public offering, the sale of equity securities and warrants in private placements, debt financing and grants. During the nine months ended September 30, 2010 and the year ended December 31, 2009, our operating activities used cash of \$5,135,605 and \$5,799,481, respectively. The use of cash in all periods primarily resulted from our net losses adjusted for non-cash items and changes in operating assets and liabilities. We had negative working capital of \$510,644 as of September 30, 2010 compared to positive working capital of \$2,564,147 as of December 31, 2009.

During the nine months ended September 30, 2010 and the year ended December 31, 2009, our investing activities used cash and provided cash of \$179,380 and \$30,927, respectively. The cash provided and used in connection with investing activities primarily related to purchases and sales of equipment.

During the nine months ended September 30, 2010 and the years ended December 31, 2009, our financing activities provided cash of \$5,518,609 and \$4,904,213, respectively. The cash provided by financing activities in the year ended December 31, 2009 was primarily due to our debt and equity financings including the June 2009 Private Placement and the December 2009 Private Placement. The cash provided by investing activities in the nine months ended September 30, 2010 was primarily due to the release of restrictions on cash, borrowings under a note payable from a shareholder, offset by reductions in long term notes payable and reductions in proceeds from issuances of common stock.

Additional details of our financing activities are provided below:

### ***June 2009 Private Placement***

On June 29, 2009, we issued a total of 2,500,000 shares of restricted common stock and warrants to acquire 50,000 shares of common stock in a private placement to the Koski Family Limited Partnership, or KFLP, for total proceeds of \$4,000,000 (the "June 2009 Private Placement"). The shares were sold at \$1.60 per share. The warrants to purchase 50,000 shares of our common stock were exercisable at \$2.00 per share and had a five year term. The consideration paid by the KFLP for the shares of common stock consisted of \$4,000,000 as follows: \$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. In addition, pursuant to the securities purchase agreement (the "June 2009 Purchase Agreement") with the KFLP, the KFLP also provided a secured loan of \$1,000,000 to us. The loan was secured by substantially all of our assets, excluding receivables, and paid interest at the rate of prime plus 4.0% which was payable quarterly. This loan was subsequently repaid by us in connection with the December 2009 Private Placement described below. The principal of the loan was due in five years. As a result of the June 2009 Private Placement the Board of Directors believes there was a change of control, with the KFLP acquiring a controlling interest in our outstanding voting common stock. We also agreed to provide the KFLP with certain registration rights in connection with any underwritten or other offering by us over the next five years. Specifically, we are obligated to register on behalf of the KFLP shares of common stock held by the KFLP equal to 15% of the total number of shares of common stock to be sold by us in a public offering subject to the discretion of the managing underwriter on the inclusion of shares in the offering to be sold by selling shareholders.

In addition to the above, as a further condition to the consummation of the transaction contemplated by the June 2009 Purchase Agreement, we were required to obtain satisfactory arrangements with three main creditors for reductions in the amounts payable by us to these creditors. As of June 30, 2009, these reductions amounted to \$707,674 in the aggregate and were conditioned upon prompt payment of the remaining balances owed to such creditors after taking into account the agreed upon reductions. As of December 31, 2009, the amount of reductions arranged with our creditors totaled \$832,959. These agreed upon reductions in payables have been fully reflected in our financial statements for the periods and reported under other income.

In connection with, and as a closing condition to the June 2009 Private Placement, the purchasers in the June 2008 Private Placement (including George Hawes, our largest shareholder prior to the June 2009 Private Placement), entered into a consent, waiver and mutual release agreement with us on June 25, 2009. In addition, the purchasers in the June 2008 Private Placement waived and relinquished any special rights they possessed pursuant to the agreements with us as part of the June 2008 Private Placement, including, but not limited to, (i) rights of first refusal, (ii) antidilution regarding future equity sales and (iii) covenants regarding secured lending by us. In connection with such consents, waivers and mutual releases, warrants to acquire 161,000 shares that were previously issued in connection with the June 2008 Private Placement 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 \$26.00 to \$15.00. In addition, to the extent of

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any future underwritten registered offerings of our common stock, or the filing of any resale registration statement by us, in each case occurring within five years from the date of the consent, waiver and mutual release, the purchasers shall have the right to include an aggregate of up to 5.0% of the shares being registered in such offering or registration statement, subject to the discretion, in any underwritten primary offerings by us, of the underwriter on the inclusion of shares in the offering to be sold by selling shareholders.

### ***December 2009 Private Placement***

On December 30, 2009, we issued a total of 500,812 shares of restricted common stock in the initial closing of a private placement to accredited investors including the KFLP, our largest shareholder (the “December 2009 Private Placement”), for initial proceeds of \$2,504,062. The shares were sold at \$5.00 per share. The initial closing proceeds of \$2,504,062 included the cancellation at closing of \$54,062 in outstanding obligations we owed to Dr. Jeffrey Hillman, our Chief Scientific Officer, for compensation that had been deferred. Approximately half of the total investment, or \$1,250,000, was made by the KFLP. In conjunction with, and as a condition to the initial closing of the December 2009 Private Placement, we also issued 200,000 shares of our common stock to the KFLP at \$5.00 per share, which was the same price per share paid by the participating accredited investors, in exchange for the cancellation of the KFLP’s \$1,000,000 secured promissory note we previously issued to the KFLP in connection with the June 2009 Private Placement.

Approximately \$1,000,000 of the total proceeds from the December 2009 Private Placement were committed to further our development of the DPOLT synthetic chemistry platform, essential to the production of our lead antibiotic, MU1140, subject to the goals set forth by the two-year NSF SBIR Phase II grant that we received on February 15, 2008. Such allocation enabled us to be eligible to receive up to an additional \$500,000 matching grant from the NSF, which grant was subsequently awarded in June 2010.

Contemporaneously with the initial closing of the December 2009 Private Placement, the KFLP also elected to exercise warrants it received as part of the June 2009 Private Placement to purchase 50,000 shares of our common stock. The warrants were exercised through the payment by the KFLP of the warrant exercise price of \$2.00 per share. Additionally, Christine Koski and Robert Koski, as directors, each exercised previously issued options to purchase 5,000 shares of our common stock at the option exercise price of \$2.00 per share. These options were granted to Christine Koski and Robert Koski when they became non-employee directors on June 30, 2009 in connection with our non-employee director compensation program.

On January 13, 2010, we completed the \$3,004,062 private placement contemplated by the December 2009 Private Placement and issued another 100,000 shares of common stock at a price per share of \$5.00 to the accredited investors for \$500,000. Of this amount, the KFLP again participated in half of the remainder of the aggregate investment by acquiring 50,000 shares for \$250,000.

### ***May 2010 Note Financing***

On May 28, 2010, we entered into an unsecured promissory note with a conversion provision (the “May 2010 Note”) to the KFLP pursuant to which we borrowed \$1,000,000 from the KFLP. Interest on the May 2010 Note accrued at the rate of LIBOR plus 6.0% and the principal of the May 2010 Note, together with all accrued interest thereon, was due and payable the earlier of: (i) the closing date of a registered public offering of newly issued equity securities by us resulting in cash proceeds to us, other than in connection with employee option plans, or (ii) the May 24, 2011 maturity date; provided, however, that in the event we completed a subsequent private offering of equity securities prior to the May 24, 2011 maturity date, we could elect to convert the principal of the May 2010 Note into the same equity securities being sold in the private offering at the same price and terms to the KFLP.

### ***July 2010 Financing Transaction***

On July 5, 2010, we entered into a common stock purchase agreement (the “July 2010 Financing Transaction”) with the Koski Family Limited Partnership, or KFLP. At the closing of this financing transaction on July 30, 2010 we issued 250,000 shares of our common stock to the KFLP at a price of \$8.00 per share. The \$2,000,000 aggregate consideration paid by the KFLP consisted of (i) \$1,000,000 cash and (ii) the exchange and cancellation of the outstanding May 2010 Note issued to the KFLP on May 28, 2010. Accrued interest on the May 2010 Note through closing was waived by the

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KFLP. Concurrent with the July 2010 Financing Transaction and as part thereof, we entered into an unsecured revolving credit agreement (the "Credit Facility") with the KFLP. Pursuant to the Credit Facility, we are able to borrow up to \$2,000,000 from the KFLP at LIBOR plus 6.0%. The term of the Credit Facility is for 12 months commencing August 1, 2010. On September 13, 2010, the Company drew down on the Credit Facility in the amount of one million dollars \$1,000,000 and executed a Revolving Unsecured Promissory Note (the "September Promissory Note") for such amount in favor of the KFLP. In addition, on November 8, 2010 the Company drew down on the remaining \$1.0 million of available funds under the Credit Facility and executed another Revolving Unsecured Promissory Note (the "November Promissory Note"). The September Promissory Note and November Promissory Note each mature on July 30, 2011.

### **Other Financings**

On March 17, 2009, we entered into a short-term note payable for \$53,087 with an interest rate of 5.75% to finance product liability insurance. This note required principal and interest payments to be made evenly over a ten-month period and was repaid in full at December 31, 2009.

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. The note included an interest rate of 15% per annum and its maturity date was April 15, 2011. On August 21, 2009 we repaid this short-term note and outstanding accrued interest in full. In connection with this borrowing we also issued warrants to acquire 5,000 shares of our common stock at an exercise price of \$10.00 per share to the investor and such warrants are exercisable for five years.

On May 4, 2009 and June 10, 2009, we borrowed \$32,556 and \$13,100, respectively, from Dr. Jeffery Hillman, our founder, Chief Scientific 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 Healthcare 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 22,828 shares of our common stock at a price of \$2.00 per share, which was the closing price of our common stock on June 29, 2009.

On August 6, 2009 we entered into a short-term note payable for \$70,025 with an interest rate of 5.75% to finance directors' and officers' liability insurance. This note required principal and interest payments to be made evenly over a ten-month period and was repaid in full on May 24, 2010 in accordance with its terms.

On March 17, 2010, we entered into a short-term note payable for \$50,637 with an interest rate of 5.75% to finance product liability insurance. Payments on this note are made evenly based on a straight line amortization over a ten-month period with the final payment due on January 10, 2011. At June 30, 2010 the outstanding balance due was \$30,382.

On July 9, 2010, we entered into a non-interest bearing short-term note payable for \$22,188 to finance a portion of our new enterprise resource planning system. Payments on this note began July 9, 2010 and are made quarterly with the final payment due on April 1, 2011.

On July 20, 2010 we entered into a short-term note payable for \$65,529 with an interest rate of 5.75% to finance directors' and officers' liability insurance. Payments on this note begin on August 24, 2010 and are made evenly based upon a straight line amortization over a ten-month period with the final payment due on July 24, 2011.

On July 31, 2010, we entered into a short-term note payable for \$85,185 bearing interest at 7.5% to finance a portion our new enterprise resource planning system. Principal and interest payments on this note begin August 31, 2010 and are made evenly based on a straight line amortization over a 17-month period with the final payment due on December 31, 2011.

### **Grants**

On February 15, 2008, we were awarded a two-year NSF SBIR Phase II grant to advance development of DPOLT. This federal grant supports studies focused on the synthesis and testing of our lead antibiotic, MU1140. While the grant will total \$500,000, to date we have received \$425,000 of these restricted funds.

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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 biomarker technology.

On June 14, 2010 we were awarded the matching \$500,000 grant from the NSF to support the previously awarded SBIR Phase II grant for further development of our DPOLT platform. On June 17, 2010, we received \$125,000 of a \$500,000 NSF awarded SBIR II Phase II grant for the company's DPOLT platform. Proceeds from the financing are to be allocated to further the development of our DPOLT platform, essential to the production of our lead antibiotic, MU1140, subject to the goals set forth by the NSF SBIR Phase II grant received by us. The remainder of these grant funds are expected to be provided to us in \$125,000 increments over the next 18 to 24 months.

On November 1, 2010, the Company received notification that it will receive federal grant funding for three of its therapeutic development programs under the Qualifying Therapeutic Discovery Project. The Qualifying Therapeutic Discovery Project, was recently enacted by Congress as part of the Patient Protection and Affordable Care Act of 2010, which was designed to provide grants or tax credits to qualified biotechnology companies that demonstrate the potential to either 1) develop new therapies to treat areas of unmet medical needs; 2) prevent, detect or treat chronic or acute diseases and conditions; 3) reduce long-term health care costs in United States; or 4) significantly advance the goal of curing cancer within the 30 year period beginning on May 21, 2010. The Company applied for funding on three of its programs: Prevention of Tooth Decay using Smart Replacement Therapy, Novel Antibiotics for the Treatment of Healthcare Associated Infections and Rapid and Sensitive Identification of Novel Diagnostic Biomarkers for Cancer and Infectious Diseases. The Company will receive a non-taxable cash grant award totaling \$733,437 under the program. A payment of \$371,219 has been authorized to be made to the Company in November 2010 and the remaining grant award amount of \$362,218 will be authorized for payment to the Company no later than 30 days after the end of the calendar year ending December 31, 2010.

### **Future Capital Requirements**

Our capital requirements for the remainder of 2010 will depend on numerous factors, including the success of our commercialization efforts and of our research and development, the resources we devote to develop and support our technologies and the success of pursuing strategic licensing and funded product development relationships with external partners. Subject to our ability to generate revenues and cash flow from our ProBiora3 products and our ability to raise additional capital including through possible joint ventures and/or partnerships, we expect 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 our capital raising efforts and being a public company. We will require substantial funds to conduct research and development and preclinical and Phase 1 clinical testing of our licensed, patented technologies and to develop sublicensing relationships for the Phase 2 and 3 clinical testing and manufacture and marketing of any products that are approved for commercial sale. Our plans include seeking both equity and debt financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to ensure continuation of our operations and research and development programs.

In addition, the report of our independent registered public accounting firm with respect to our financial statements appearing in our Form 10-K contains an explanatory paragraph stating that our operating losses and negative cash flows from operations since inception, and our need to raise additional financing and/or financial support prior to December 31, 2010 in order to continue to fund our operations, raise substantial doubt about our ability to continue as a going concern. If we are unable to raise sufficient capital we will need to significantly modify our operational plans for us to continue as a going concern.

Our current available cash and cash equivalents are insufficient to satisfy our liquidity requirements. We believe our existing cash and cash equivalents together with the borrowings under our Credit Facility and grant funds will allow us to fund our operating plan through the end of the year. We will need to raise capital through the additional sale of equity or debt securities. The sale of additional equity or debt securities may result in additional dilution to our shareholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We also require additional capital beyond our currently forecasted amounts, such as, for example, if we determine to proceed independently with a Phase 3 clinical trial for our SMaRT Replacement Therapy. Any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be

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required to reduce the scope of, delay or eliminate some or all of our planned clinical testing, research and development and commercialization activities, which could harm our business.

Because of the numerous risks and uncertainties associated with sales of our ProBiora3 products as well as research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the cash flow generated from our ProBiora3 product sales;
- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities for our ProBiora3 products and, if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our ProBiora3 products and product candidates and any products we successfully commercialize;
- our ability to establish strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our products and future products, if any.

### **Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements.

### **Tax Loss Carryforwards**

As of December 31, 2009, we have net operating loss carryforwards of approximately \$23,000,000 to offset future federal and state income taxes. We also have research and development and investment tax credit carryforwards of approximately \$400,000 to offset future federal and state income taxes. Any greater than 50% change in ownership under Section 382 of the Internal Revenue Code, or the Code, places significant annual limitations on the use of such net operating loss carryforwards and we exceeded the 50% threshold when we consummated the June 2009 Private Placement transaction with the KFLP. As a result, our historical loss carryforwards through June 2009 will be limited to \$172,000 per year over the next 20 years, or limited to an aggregate amount of up to \$3,440,000 of such historical loss carryforwards over such period of time, and the remaining balance of our historical loss carryforwards prior to June 2009 will expire unused. Provided that there are no future ownership changes that would trigger the limitations on loss carryforwards provided under the Code, the operating losses we experience after the June 2009 Private Placement transaction are expected to add to our loss carryforwards and to be fully available to us.

At December 31, 2009, we recorded a 100% valuation allowance against our deferred tax assets of approximately \$8,700,000, as our management believes it is uncertain that they will be fully realized. If we determine in the future that we will be able to realize all or a portion of our net operating loss carryforwards, an adjustment to our net operating loss carryforwards would increase net income in the period in which we make such a determination.

## **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 Chief Financial Officer, to allow timely decisions regarding required disclosures.

As previously disclosed under Item 4T, *Controls and Procedures*, in our Quarterly Reports on Form 10-Q for the quarter ended September 30, 2009 we identified several material weaknesses in our internal controls. Since that time we have been working on remediation of the identified material weaknesses and have provided updates in our Form 10Q for the period ended September 30, 2009 and our Form 10K for the period ended December 31, 2009 (See Item 9A(T) *Controls and Procedures*). Management believes progress has been made during the quarter to remediate material weaknesses in the internal control over financial reporting. Based on the continued existence of material weaknesses, however, our Chief Executive Officer and Principal Financial Officer have concluded that, as of the quarter ended September 30, 2010, 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 September 30, 2010 Form 10-Q fairly presented, in all material respects, our financial position, results of operations, and cash flows for the periods presented in conformity with GAAP.

As previously disclosed and referenced above, the matters involving internal controls and procedures that our management identified and considered to be material weaknesses that have not yet been satisfactorily remediated are: (1) limited documentation of our system of internal control, (2) insufficient personnel to employ segregation of duties; (3) 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; (4) deficiencies in our material technology systems. These deficiencies and weaknesses were largely attributable to the significant lack of available financial resources.

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

Although management has not fully remediated all the material weaknesses mentioned above, management believes progress has been made. For example, during the third quarter we have acquired a new business operating system to provided more data controls, improved business processes, process documentation and better financial reporting. The new system is expected to be operational during November, 2010. We also continued the engagement with 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 evaluation of the treasury and payroll cycles. Following such evaluation, management implemented a remediation plan during the quarter and addressed the documentation and authority levels of our treasury and payroll controls. Management also expects to review various facets of our information processing system, such as sales and billing, inventory, materials management 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 resources and available liquidity permit. 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.

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

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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.

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**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, 2009 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, 2009 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. The specific risk factors set forth below were included in our Form 10-K Risk Factors and have been updated to provide information as of June 30, 2010. 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, 2009.

You should carefully consider the Risk Factors and 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 continue to require additional financing to operate beyond year end 2010.***

We do not have sufficient capital to sustain our operations beyond the end of 2010 and we require additional financing. If we are not able to raise additional capital, among other things, we could:

- need to scale back or cease our marketing and development efforts;
- be forced to cease operations;
- be unable to pursue clinical testing and 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;
- have our licenses for our SMaRT™ Replacement Therapy technology and MU 1140 technology terminated; and
- be forced to reorganize under the protection of the Federal Bankruptcy Laws.

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



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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 modest 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 commercialization, marketing and research and development initiatives. We expect to incur losses for at least the next several quarters as we seek to expand our sales and marketing capabilities, make use of the sales and marketing capabilities of third parties and attempt to continue our clinical trials and research and development activities. Losses have totaled:

\$5,632,650 for the nine months ended September 30, 2010

\$5,519,348 for the year ended December 31, 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 shareholders' (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, 2009 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 not earned significant revenue from operations and we have an accumulated deficit of \$31,144,532 as of September 30, 2010 and \$25,511,883 as of December 31, 2009. We have an operating cash flow deficit of \$5,135,607 for the nine months ended September 30, 2010 and \$5,799,481 for the year ended December 31, 2009 and we sustained operating cash flow deficits of \$3,835,190 and \$1,913,760 in 2008 and 2007, respectively. Our accounts payable and accrued expenses have also increased due to operational changes instituted in connection with the launch of our consumer products and in connection with our abandoned public offering. At September 30, 2010, December 31, 2009 and December 31, 2008, we had working capital (deficit) of (\$510,644), \$2,564,147 and (\$500,672), respectively.

### **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" in our Form 10-K and in this 10-Q. 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**

**None.**

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**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

**None.**

**ITEM 4. (Reserved)**

**Not Applicable.**

**ITEM 5. OTHER INFORMATION**

The disclosure set forth below is provided in lieu of a separate Form 8-K filing.

Oragenics, Inc. (the “Company”) previously announced that it had (i) entered into an unsecured revolving credit agreement (the “Credit Facility”) with the Koski Family Limited Partnership (“KFLP”) on July 30, 2010 and (ii) drew down \$1.0 million on the Credit Facility on September 13, 2010 and executed a Revolving Unsecured Promissory Note (the “September Promissory Note”). Pursuant to the Credit Facility the Company was able to borrow up to \$2.0 million from the KFLP at LIBOR plus 6.0%, subject to certain conditions precedent, including compliance with the Credit Facility. The term of the Credit Facility is for twelve months commencing August 1, 2010.

On November 8, 2010, the Company drew down on the remaining available funds under the Credit Facility in the amount of one million dollars (\$1,000,000) and executed another Revolving Unsecured Promissory Note (the “November Promissory Note”) for such amount in favor of the KFLP. The September Promissory Note and November Promissory Note each mature on July 30, 2011.

**ITEM 6. EXHIBITS**

Incorporated by reference to Exhibits filed after signature page.

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**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 12 day of November, 2010.

**ORAGENICS, INC.**

BY: /s/ David B. Hirsch

David B. Hirsch, President and Chief Executive  
Officer  
(Principal Executive Officer)

/s/ Brian Bohunicky

Brian Bohunicky  
Chief Financial Officer  
(Principal Financial Officer)

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<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Form</b>	<b>File No</b>	<b>Exhibit</b>	<b>Filing Date</b>	<b>Filed Herewith</b>
3.1	Amended and Restated Articles of Organization	SB-2	333-100568	3.3	10/16/02	
3.2	Articles of Amendment to Amended and Restated Articles of Incorporation	8-K	001-32188	10.2	10/30/09	
3.3	Articles of Amendment to Amended and Restated Articles of Organization	8-K	001-32188	3.1	9/29/10	
3.4	Bylaws	SB-2	333-100568	4.1	10/16/02	
3.5	First Amendment to Bylaws	8-K	00132188	3.2	6/9/10	
3.6	Second Amendment to Bylaws	8-K	001-32188	3.1	8/24/10	
10.1	Common Stock Purchase Agreement	8-K	001-32188	10.1	7/7/10	
10.2	Revolving Credit Agreement	8-K	001-32188	10.2	8/2/10	
10.3	Revolving Unsecured Promissory Note (September)	8-K	001-32188	10.2	9/16/10	
10.4	Revolving Unsecured Promissory Note (November)					X
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

## REVOLVING UNSECURED PROMISSORY NOTE

\$1,000,000

Tampa, Florida  
November 8, 2010

FOR VALUE RECEIVED, ORAGENICS, INC., a Florida corporation located at 3000 Bayport Drive, Suite 685, Tampa, Florida 32607 ("Borrower"), hereby promises to pay to the order of KOSKI FAMILY LIMITED PARTNERSHIP, a Texas limited partnership having a mailing address of 3525 Turtle Creek Boulevard, Unit 19-B, Dallas, Texas 75219 ("Lender"), the sum of One Million Dollars (\$1,000,000), together with interest thereon as provided herein. All sums are payable by personal delivery or by mail to Lender at the address listed above, or at such other address as Lender may designate to Borrower. This note is provided pursuant to the Revolving Credit Agreement of July 30, 2010 by and between Lender and Borrower.

1. Interest. The unpaid principal balance under this Revolving Unsecured Promissory Note ("Promissory Note") shall bear interest from the date hereof at an annual rate equal to the London Interbank Offered Rate (LIBOR) plus six percent (6%) (the "Applicable Rate"). The Applicable Rate shall be adjusted quarterly on the first day of each calendar quarter while any principal balance hereunder remains unpaid, based on the LIBOR in effect on the business day immediately preceding such adjustment date.
2. Payment of Principal and Interest. The principal of this Promissory Note, together with all accrued interest thereon, shall be due and payable on July 30, 2011. Any portion of the principal of this Promissory Note may be prepaid, together with the accrued interest with respect to such principal payment, prior to maturity, without penalty. Any payment made under this Promissory Note shall be applied first to accrued interest and then to principal. Payment of principal and interest shall be made in such coin or currency of the United States of America that, at the time of payment, constitutes legal tender for the payment of public and private debt.
3. Events of Default. The occurrence of any of the following events shall constitute an "Event of Default":
  - (a) the failure of Borrower to pay all or any portion of the principal and interest due and payable under this Promissory Note and such failure continues for five (5) business days after the Lender notifies Borrower in writing of such failure;
  - (b) the filing against Borrower of an involuntary petition or other pleading seeking the entry of a decree or order for relief under the United States Bankruptcy Code or any similar federal or state insolvency or other similar law ordering: (i) the liquidation of Borrower, (ii) a reorganization of Borrower or the business and affairs of Borrower, or (iii) the appointment of a receiver, liquidator, assignee, custodian, trustee or similar official for Borrower or the property of Borrower, and the failure to have such petition or other pleading denied or dismissed within thirty (30) days from the date of filing;
  - (c) the commencement by Borrower of a voluntary case under the United States Bankruptcy Code or any similar federal or state insolvency or other similar law, (ii) the consent by Borrower to the appointment or taking possession by a receiver, liquidator, assignee, trustee, custodian or similar official for Borrower or any of the property of Borrower, or (iii) the making by Borrower of an assignment for the benefit of creditors.
  - (d) the breach of any term of any of the Loan Documents as defined in that Revolving Credit Agreement of July 30, 2010 by and between Borrower and Lender ("Loan Documents").
4. Rights and Remedies Upon Default. Upon the occurrence of an Event of Default, the principal and all accrued but unpaid interest due under this Promissory Note shall, at the option of Lender, become immediately due and payable and may be collected forthwith without notice to Borrower, regardless of the stipulated date of maturity and, in that event, Borrower promises to pay, in addition to the unpaid principal and interest hereunder, all costs, including reasonable attorneys' fees, paralegals' fees and expenses for any primary, appellate, bankruptcy and post-judgment

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proceedings, that Lender may incur or be put to in the collection of such amounts. Any overdue payment of principal or interest due under this Promissory Note shall bear interest from the due date at twelve percent (12%) per annum.

5. Waiver. Borrower hereby waives protest, demand, presentment and notice of dishonor, notice of the maturity, nonpayment, and all requirements necessary to hold it liable as the maker of this Promissory Note, and agrees that this Promissory Note may be extended in whole or in part without limit as to the number of such extensions or the period or periods thereof, and without notice to it and without affecting its liability hereunder. Failure to accelerate the debt in the event of any default hereunder, or other indulgence granted from time to time, shall not be construed as a novation of this Promissory Note or a waiver of the right of Lender to thereafter insist upon strict compliance with the terms of this Promissory Note without previous written notice of such intention being given to Borrower.
6. Compliance With Usury Laws. All agreements between Borrower and Lender are hereby expressly limited so that in no event shall the amount paid or agreed to be paid to Lender for the use, forbearance, or detention of the money loaned under this Promissory Note exceed the maximum amount permissible under the laws of the State of Florida. If, at the time of any interest payment, the payment amount due under this Promissory Note is in excess of the legal limit, the obligation shall be reduced to the legal limit. If Borrower should ever receive, as interest, an amount that exceeds the highest lawful rate, the amount that would be excessive as interest shall be applied to the reduction of the principal amount owing under this Promissory Note, and not to the payment of interest.
7. Waiver of Jury Trial. BORROWER HEREBY KNOWINGLY, VOLUNTARILY AND INTENTIONALLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LITIGATION BASED HEREON, OR ARISING OUT OF, UNDER OR IN CONJUNCTION WITH, THIS PROMISSORY NOTE AND ANY OTHER AGREEMENT CONTEMPLATED TO BE EXECUTED IN CONJUNCTION HEREWITH, OR ANY COURSE OF CONDUCT, COURSE OF DEALING, STATEMENTS (WHETHER VERBAL OR WRITTEN) OR ACTIONS OF EITHER PARTY.
8. Choice of Law; Venue. The laws of the State of Florida, excluding its choice of law provisions if such laws would result in the application of laws other than the laws of the State of Florida, shall govern any disputes with respect to this Promissory Note, the validity of this Promissory Note, the construction of its terms, and the interpretation of the rights and duties of Borrower and Lender hereunder. The forum selected for any proceeding or suit related to a dispute between Borrower and Lender related to this Promissory Note shall be in a federal or state court of competent jurisdiction located in Hillsborough County, Florida. Borrower consents to said courts' personal jurisdiction over it and waives any defense, whether asserted by motion or pleading, that Hillsborough County, Florida is an improper or inconvenient venue.
9. Notice. Any notice, demand or other communication to Borrower that is permitted or required hereunder shall be given in writing, and shall be deemed to have been duly delivered (i) when delivered by personal delivery, (ii) three (3) days after being deposited with the United States Postal Service for mailing by first class mail, postage prepaid, certified mail, with return receipt requested (regardless of whether the return receipt is subsequently received), or (iii) one business day after being deposited with a nationally recognized courier service for overnight delivery; and in each case addressed by Lender to Borrower at the address for Borrower first listed above, or to such other address as Borrower may notify Lender in writing in conformity with the provisions of this Section.
10. Documentary Stamp Taxes. Borrower shall pay all documentary stamp taxes due on the obligation evidenced by this Promissory Note.
11. Assignment. Lender may assign all or any portion of this Promissory Note and Lender's rights thereunder.
12. Binding Effect. This Promissory Note shall be binding upon Borrower and its successors and assigns, and shall inure to the benefit of Lender and its successors and assigns.
13. Computation of Time. Whenever the last day for payment of any amount due hereunder shall fall upon Saturday, Sunday or any public or legal holiday, whether federal or of the State of Florida, Borrower shall have until 5:00 p.m. on the next succeeding regular business day to make such payment.

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IN WITNESS WHEREOF, Borrower has executed this Promissory Note on the date indicated below.

**ORAGENICS, INC.**

By: /s/ Brian Bohunicky

Name: Brian Bohunicky

Title: Chief Financial Officer

Date: November 8, 2010

## 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 12, 2010

/s/ David B. Hirsch

David B. Hirsch, President and Chief Executive Officer



## 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 12, 2010

/s/ Brian J. Bohunicky

Brian J. Bohunicky, Chief Financial Officer

**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, 2010 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 12 day of November, 2010.

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

**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, 2010 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 12 day of November, 2010.

/s/ Brian J. Bohunicky

Brian J. Bohunicky  
Chief Financial Officer