



# **OSTA BIOTECHNOLOGIES INC.**

## **Management's Discussion and Analysis**

**For the three month period ended  
March 31, 2009**

## **INTRODUCTION**

The following discussion is management's analysis of the consolidated operating and financial data for Osta Biotechnologies Inc. (the "Company") and its wholly owned subsidiary, Osta BioPharma Inc. ("Osta"), for the three month period ended March 31, 2008. It should be read in conjunction with the accompanying consolidated unaudited financial statements and related notes for the three month period ended March 31, 2008 prepared in accordance with Canadian generally accepted accounting principles taking into account material events up to May 27, 2009. All amounts are expressed in Canadian dollars.

### **Inherent Risk Factors**

The Company's products and technologies are currently in the research and developmental stage. The Company does not and may never have commercially viable products approved for commercialization. To date, the Company has not generated any revenues from sales. The Company's financial condition will depend on its ability to obtain additional funding through the capital markets. The availability of such funding may not be under favorable terms or may not be available at all. The ability of the Company to successfully obtain additional financing in the future will depend partly on the condition of capital markets at the time and partly of the future performance of the Company.

### **Forward Looking Statements**

The following discussion contains forward looking statements regarding the Company's financial condition and the results of operation that are based on its consolidated financial statements. The Company operates in a highly competitive environment that involves significant risks and uncertainties, some of which are outside the Company's control. The Company is subject to risks inherent in the biopharmaceutical industry, including risks associated with research, preclinical testing, manufacture of drug substance to support clinical studies, toxicology studies, uncertainty of regulatory agencies, enforcement and protection of the Company's patent portfolio, the need for future capital, potential competitors, the ability to attract and maintain collaborative partners, dependence on key personnel and the ability to successfully market the Company's product candidates. The Company's actual results could differ materially from those expressed or implied in these forward looking statements. For a more detailed discussion of related risks, please refer to the Company's public filings available on [www.sedar.com](http://www.sedar.com).

## **CHANGES IN ACCOUNTING POLICIES**

In January 2008, the Canadian Institute of Chartered Accountants ("CICA") issued a new standard, Section 3064 - Goodwill and Intangible Assets, which replaced Section 3062 -

Goodwill and Other Intangible Assets, and will result in the withdrawal of Section 3450 - Research and Development Costs, as well as Emerging Issues Committee (EIC) 27 - Revenues and Expenditures During the Pre-Operating Period, and Accounting Guideline (AcG 11) - Enterprises in the Development Stage. This standard provides a guideline on the recognition of intangible assets according to the definition of an asset, application of the matching costs against revenues, whether these assets were acquired or developed internally. This section applies to annual financial statements for fiscal years beginning on or after October 1, 2008. The adoption of this new standard did not have any impact on the financial statements.

## **HARMONIZING OF CANADIAN AND INTERNATIONAL STANDARDS**

In February 2008, Canada’s Accounting Standards Board (AcSB) confirmed that Canadian GAAP, as used by publicly accountable enterprises, will be fully converged with International Financial Reporting Standards as issued by the International Accounting Standards Board (“IFRS-IASB”). The changeover date is effective for interim and annual financial reporting for fiscal year ends beginning on or after January 1, 2011. IFRS uses a conceptual framework similar to Canadian GAAP, but there are significant differences in recognition, measurement and disclosures which the Company must address. The Company is currently developing its IFRS conversion plan and evaluating the effect of these new standards on its financial statements. Determination of the key differences between IFRS and the Company’s accounting policies is in progress with an evaluation of the main potential impact on its business practices, systems and internal controls over financial reporting.

## **SELECTED FINANCIAL INFORMATION**

The selected financial information provided below is derived from our unaudited quarterly consolidated financial statements for each of the last five quarters:

<b>Summary of Quarterly results</b>						
	Net Loss			Loss per share		
Quarter	2009	2008	2007	2009	2008	2007
Q1	\$135,699	\$186,564	\$172,835	.0038	.0053	.0073
Q2		\$183,048	\$228,104		.0052	.0068
Q3		\$146,529	\$193,008		.0041	.0056
Q4		\$109,099	\$341,305		.0031	.0100

## **Consolidation of Financial Statements**

For the three month period ended March 31, 2009, the financial statements of the Company and Osta are presented on a consolidated basis. All intercompany transactions and balances have been eliminated upon consolidation.

## **Outstanding Shares**

At March 31, 2009, the Company had 35,386,528 (2007 - 35,386,528) common shares issued and outstanding. Options to acquire an aggregate of 3,175,000 common shares have been granted to directors, officers and consultants of the Company pursuant to the terms of the Company's incentive stock option plan. In addition, 8,199,717 Common Shares have been reserved for issuance pursuant to all outstanding common share purchase warrants.

On April 23, 2009, the Company issued 50,000 vested options to acquire common shares of the Company at an exercise price of \$0.10 per share to the Chief Financial Officer. An additional 25,000 non-vested options to acquire common shares of the Company at an exercise price of \$0.10 per share were issued to a consultant.

On May 13, 2009, options to acquire an aggregate 50,000 common shares at an exercise price of \$0.35 per share expired.

Other than indicated above, as of May 27, 2009, there have been no other changes to the outstanding shares and no other issuance of stock options or warrants.

## **RESULTS OF OPERATIONS**

The Company is engaged in research and development and does not have any products that are presently at commercialization stage. The Company continues to incur expenses related to research and development and as such anticipates that losses will continue until such time as the Company is able to successfully commercialize one of its products, which may never occur.

### **Investment Income**

During the three month period ended March 31, 2009, the Company had revenues of \$1,866 consisting of interest income as compared to \$10,328 for the three month period ended March 31, 2008. The decrease in revenue is due to a substantial decrease in interest rates offered by the financial institutions as well as a reduction in cash and cash equivalents available for short-term investments.

### **Expenses**

The Company had gross expenses during three month period ended March 31, 2009 of \$137,565 as compared to \$196,892 during three month period ended March 31, 2008. The decrease in gross expenses is primarily due to the stock option compensation granted to consultants of the company during the period as well as an overall reduction in

administrative labour costs (Salaries and wage levies and professional and consulting fees). In addition, the Company incurred expenses related to the refundable grant received in October 2008 from the Institute for Study of Aging (ISOA) described in the working capital analyses below. These expenses include \$6,593 of unrealized losses on foreign exchange and \$2,922 of accrued interest. As described in Note 8 to the interim unaudited financial statements, the interest will be capitalized together with the balance and is convertible to shares of the company.

### **Research and Development Expenses**

During the three months ended March 31, 2009, the Company spent \$64,053 on research and development (R&D) as compared to \$80,545 for the three month period ended March 31, 2008. These expenses are comprised of \$30,713 of salaries (March 31, 2008 - \$38,325) and \$33,340 of subcontracts (March 31, 2008 - \$42,220). The decrease in research and development expenses is due mainly to a more strategic selection of ongoing research projects resulting from a more concerted effort by management to manage cash flow requirements.

All the expenses were for the development of a novel drug for cancer and Alzheimer's disease.

### **General & Administrative Expenses**

During the three month period ended March 31, 2009, the Company spent \$83,430 on general and administrative expenses as compared to \$136,153 for the three month period ended March 31, 2008. The breakdown of these expenses is as follows:

	2009	2008
	\$	\$
Salaries and wage levies	21,147	40,950
Professional and consulting fees	40,439	28,250
Total administrative labor costs before stock option compensation	61,586	69,200
Stock option compensation	8,422	54,034
Interest on long-term convertible note	2,335	-
Unrealized loss on foreign exchange	6,593	-
	<u>78,936</u>	<u>123,234</u>
Other amounts	4,494	12,919
	<u>83,430</u>	<u>136,153</u>

The decrease in general and administrative expenses is due mainly to a lower administrative labor costs and a decrease in stock option compensation.

### **Summary of Research and Development Activities**

The Company is a biopharmaceutical Company whose principal business is to carry out

research and development work for the development of novel diagnostic and therapeutic products specific to cancer, Alzheimer's disease, XLH, osteoporosis and osteoarthritis. Based on the availability of limited funds, the company has put priorities on the development of a novel drug for cancer chemotherapy and a novel drug for the treatment of Alzheimer's disease. As a result, the company has put all other research and development programs on hold till further financing has been secured.

#### ***Cancers Therapeutic Agent***

Based on the availability of limited funds, the Company has prioritized the development of a novel anti-cancer drug and is currently focusing on developing novel therapeutic agents that could be used as adjuvant chemotherapeutic agents to treat aggressive metastatic, invasive and drug resistant tumors. The Company's lead compound has shown very promising results in pre-clinical animal models for the treatment of metastatic and hormone refractory prostate cancer. Subject to the completion of a round of financing in a timely fashion, the Company plans to complete the pre-clinical studies in 2010 and file an IND application in 2011 to initiate human clinical studies in North America. The Company expects that it will cost approximately \$2,000,000 to manufacture cGMP drug product and to complete the various pre-clinical studies.

#### ***Therapeutic Agent for treatment of Alzheimer's Disease***

The Company is developing of a novel therapeutic for the treatment of Alzheimer's disease (AD) and is at the lead optimization stage. The efficacy of the lead molecule will be evaluated using the most suitable animal model and a promising drug candidate will be taken into pre-clinical and clinical development. The Company needs additional capital to pursue the development of its AD therapeutic agent. In October 2008, the company has secured a funding of \$247,106 US from the Institute for Study of Aging (ISOA) to advance the pre-clinical development of its AD drug. Upon successful demonstration of proof of principle in-vivo and the completion of financing in a timely fashion, it plans to complete GLP non-clinical toxicology and safety pharmacology studies in 2011 and plans to file an IND application in 2012 to initiate Phase-I trials in the US. The Company expects that it will cost approximately \$2,500,000 to demonstrate proof of validation in-vivo and to complete the various pre-clinical studies required for IND filing.

#### **Results**

For the three month period ended March 31, 2009, the Company had a net loss of \$130,972 or \$0.0038 per diluted share as compared to a net loss of \$186,564 or \$0.0053 per diluted share for the same period of the previous year. The decrease in the net loss mainly resulted from a decrease in stock option compensation, a small decrease in labor costs (combined administrative salaries and professional and consulting fees) and a decrease in research and development costs. The Company expects to continue to incur losses as it continues its research and development programs.

## **Working Capital**

As at March 31 2009, the Company had cash and cash equivalents, receivables, investment tax credits receivable and prepaid expenses in the aggregate amount of \$873,360 and accounts payable and accrued liabilities of \$167,108 resulting in a working capital of \$706,252 compared to a working capital of \$1,045,411 as at December 31, 2008.

On October 21, 2008, the Company announced that it received funding from the Institute for Study of Aging (ISOA) in the form of a recoverable grant of up to \$247,106 US Dollars to develop a novel class of drugs for Alzheimer's disease. "ISOA" is a private foundation established by the Estee Lauder family in 1998. Under the terms of the refundable grant, all funds granted, and any interest or earnings earned thereon, until expended for the purposes of the project, shall not be used for any other purpose and shall not be invested in any manner that would jeopardize or impair their availability either for the use by the Company for the purpose of the project or for the return to "ISOA". Such funds shall not serve as security for any indebtedness of the Company for any money borrowed, loaned or guaranteed. Any portion of the funds not used for the purposes of the project shall be repaid to "ISOA".

As at March 31, 2009, the Company had received \$177,375 CDN Dollars (\$150,000 US Dollars) of which the unexpended balance of the funds received was approximately \$150,000 including interest earned.

Under the terms of the grant agreement with ISOA, title to any discoveries, inventions, developments, data and substances made, conceived or reduced to practice by the Company, its employees, contractors or agents during the performance of the research project or as a result of the project, including any patents, patent applications, copyrights and applications and registrations thereof, and all other intellectual property rights, title and ownership interest relating thereto will vest in the Company.

The decrease in working capital is due to the Company's on going research and development programs. Investment revenue has declined not only due to the reduced cash available for investment, but also due to the decrease in the interest rates paid by financial institutions. In addition, following the trend in the economic slowdown in the economy, the Company has not successfully completed any additional financing arrangements during the quarter.

## **Capital Resources**

The Company will need to raise additional capital in the near term. As the research and development activities increase, it is anticipated that the Company's capital requirements will also increase proportionately. At present, the Company is looking to raise additional capital through the issuance of equity. In order to manage the developmental activities

with the current cash at hand, the Company has prioritized its research and development activities on the development of a novel therapeutic agent for Alzheimer's disease (AD) as well as a novel therapeutic agent for cancer. The Company's research and development programs related to the development of a novel diagnostic test for Alzheimer's disease, a novel diagnostic & therapeutic product for osteoporosis and a novel therapeutic product for the treatment of rickets are currently a lower priority at present till further financing is secured. The Company has halted the development of novel therapeutics for osteoarthritis and aging, which may be reactivated at a later stage once further financing has been secured and the products specifically related to Alzheimer's disease and cancer have been advanced significantly. It is estimated that the Company will require approximately \$5 million in additional capital over the next two years to continue the development of the various products described above. However, there can not be any guarantee that the Company will be able to successfully raise the required capital to continue its operations or to be able to complete the various research & development milestones in a timely fashion. The Company's working capital requirements and its ability to raise additional capital are dependent on various factors, including, but not limited to, market conditions, obtaining satisfactory pre-clinical and clinical data, successfully entering into collaborations and partnerships for product development, regulatory approvals and commercialization, successfully filing patent applications and obtaining issued patents, maintaining, enforcing and defending patent claims, in-license outside patents as potentially needed, favorable outcome of regulatory review processes in a timely fashion and other factors that may be beyond the control of Management.

The Company's objectives when managing capital are:

- to safeguard the Company's ability to continue as a going concern in order to provide returns for shareholders;
- to maintain sufficient cash resources to support its ongoing research activities;
- to maintain a flexible capital structure which optimizes the cost of capital at an acceptable level of risk.

In the management of capital, the Company includes, convertible debt and shareholders' equity comprised of share capital, warrants in the equity portion of the convertible debentures, stock options, warrants, contributed surplus and deficit in the definition of capital.

The Company manages its capital structure and makes adjustments to it in light of economic conditions and the risk characteristics of the underlying assets. The Company, upon the approval of the Board of Directors, will balance its overall capital structure through the issue of new shares, the issue of new debt, acquiring or disposing of assets, or by undertaking other activities as deemed appropriate under specific circumstances. The Company has an externally imposed capital requirement related to their issue of the convertible note payable as disclosed in Note 8 to the consolidated interim unaudited financial statements. The Company's overall strategy with respect to capital risk management remains unchanged from the year ended December 31, 2008.

## **Liquidity**

As at May 27, 2009, the Company expects that its current capital resources will be sufficient to carry on its research and development plans and operations for the next 12 months. There is no assurance that the Company will continue their past success in obtaining new funding.

## **RELATED PARTY TRANSACTIONS**

During the period ended March 31, 2009, the Company paid salaries and consulting fees of approximately \$56,000 (March 31, 2008 - \$54,000) to several officers and directors for their services. These services were incurred in the normal course of operations and are measured at the exchange amount, which is the amount of consideration established and agreed to by the related parties.

## **SUBSEQUENT EVENTS**

As indicated above regarding outstanding shares, two events took place subsequent to March 31, 2009.

On April 23, 2009, the Company issued 50,000 vested options to acquire common shares of the Company at an exercise price of \$0.10 per share to the Chief Financial Officer. An additional 25,000 non-vested options to acquire common shares of the Company at an exercise price of \$0.10 per share were issued to a consultant.

On May 13, 2009, options to acquire an aggregate of 50,000 common shares at an exercise price of \$0.35 per share expired.

## **FINANCIAL INSTRUMENTS**

The Company's financial instruments are comprised of cash and cash equivalents, receivables, accounts payable and accrued liabilities and convertible debt. These financial instruments are discussed in Note 15 to the consolidated interim unaudited financial statements.

## **OUTLOOK**

At present the Company is a research and development company that has yet to generate any revenues. The Company is expected to continue to incur operating losses as it continues with the research and development of various products. The Company is currently focusing on the completion of currently on-going pre-clinical studies for the development of a novel therapeutic agent for Alzheimer's disease (AD) and pending successful completion of these studies and a successful completion of financing, the

Company plans to complete the required pre-clinical toxicology and safety pharmacology studies to support the filing of an IND application to initiate human clinical trials. In addition, the Company is continuing the development of a novel therapeutic agent for prostate cancer and expects to initiate pre-clinical toxicology and safety pharmacology studies required for IND filing as soon as it has successfully raised funds required for these studies. The Company is looking to raise additional capital by way of equity financings in order to continue the development of its products and it is anticipated that the total expenses will increase during fiscal 2009 should the Company successfully complete such additional financings.

## **MANAGEMENTS' REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING**

Management, including the President, Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Multilateral Instrument 52-109 of the Canadian Securities Administrators) as of December 31, 2008.

Management has concluded that, as of March 31, 2009, the Company's disclosure controls and procedures were effective to provide reasonable assurance that material information relating to the Company would be made known to them by others within the Company and its subsidiaries, particularly during the period in which this report was being prepared.

Management is responsible for and has designed internal controls over financial reporting to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with Canadian GAAP. There were no changes in internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.