



## **OSTA BIOTECHNOLOGIES INC.**

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

**For the second quarter ended  
June 30, 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 second quarter ended June 30, 2009. It should be read in conjunction with the accompanying unaudited consolidated interim financial statements and related notes for the second quarter ended June 30, 2009 prepared in accordance with Canadian generally accepted accounting principles taking into account material events up to August 20, 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:

<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	\$284,913	\$183,048	\$228,104	.0081	.0052	.0068
Q3		\$146,529	\$193,008		.0041	.0056
Q4		\$109,099	\$341,305		.0031	.0100

## **Consolidation of Financial Statements**

For the six month period ended June 30, 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 June 30, 2009, the Company had 35,386,528 common shares issued and outstanding. Options to acquire an aggregate of 3,750,000 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, 5,088,945 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.

On June 18, 2009, the Company issued 550,000 vested options to acquire common shares of the Company at an exercise price of \$0.18 per share to the Directors including 175,000 options to acquire Common shares to the Chief Executive Officer.

Other than indicated above, as of August 20, 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.

In consideration of the limited cash resources of the Company, the results of operations reflect a decision by the Company to prioritize its research activities on Cancer and Alzheimer's disease, and the Company has decided to discontinue several non priority patent applications during the quarter. Accordingly, a charge of \$50,901 to write-off those patent applications has been reflected in the financial statements. In addition, due to the increase in the Canadian dollar during the quarter, the Company has incurred an unrealized gain in foreign exchange of \$14,843 resulting from the decrease in Canadian dollar value of the convertible debt repayable in US funds as described in Note 8 to the financial statements.

## **Investment Income**

During the six month period ended June 30, 2009, the Company had revenues of \$2,402 consisting of interest income as compared to \$18,048 for the six month period ended June 30, 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 (before adjustment for write-offs of patents and unrealized gain on foreign exchange) during three month period ended June 30, 2009 of \$249,391 as compared to \$190,768 during three month period ended June 30, 2008. The increase in the expenses is due primarily to the stock option compensation which is a non-cash expense resulting from the issue of stock options to officers, directors and consultants of the company during the quarter. 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 \$2,167 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 common shares of the company. These increases were offset by a decrease in other expenses such as research and development (due to the completion of certain research contracts) and an overall reduction in administrative salaries and wage levies.

During the six month period ended June 30, 2009, gross expenses were \$380,363 as compared to \$387,660 for the six month period ended June 30, 2008. As indicated above, stock option compensation increased during the six month period from \$88,887 to \$117,286. This \$28,000 increase represents a non-cash expenditure resulting from the issue of stock options to directors, officers and consultants of the Company. The other significant increase in expenses during the six month period was interest on the convertible debt described above and the accrual of royalty fees on licensing agreements. The remainder of the expenses were decreased due to the completion of research contracts, the reduction in administrative salaries and a concerted effort by management to continue to optimize the resources of the Company by reducing administrative costs and focusing the research on the cancer and Alzheimer's programs.

## **Research and Development Expenses**

During three month period ended June 30, 2009, the Company spent \$76,579 on research and development as compared to \$81,506 for the three months ended June 30, 2008. These expenses are comprised of \$30,713 of salaries (June 30, 2008 - \$62,529) and \$45,866 of subcontracts (June 30, 2008 - \$18,977).

The decrease in research and development expenses is due mainly to a prioritization of ongoing research projects resulting from a more concerted effort by management to manage cash flow requirements.

During the six month period ended June 30, 2009, research and development expenses totaled \$140,631 as compared to \$162,051 for the six month period ended June 30, 2008. These expenses are comprised of \$61,425 of salaries (June 30, 2008 - \$100,853) and \$79,206 of subcontracts (June 30, 2008 - \$61,198).

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

### General & Administrative Expenses

During the three month period ended June 30, 2009, the Company incurred \$221,170 of general and administrative expenses as compared to \$131,196 for the three month period ended June 30, 2008. These expenses are summarized as follows:

	Three months ended June 30, 2009 \$	Three months ended June 30,2008 \$
Salaries and wage levies	17,912	45,743
Professional and consulting fees	36,522	36,299
Royalties	5,833	-
Stock option compensation	108,864	34,853
Interest on long-term convertible note	2,167	-
Unrealized gain on foreign exchange	-14,843	-
	<u>156,455</u>	<u>116,895</u>
Other amounts	13,814	14,301
	<u>170,269</u>	<u>131,196</u>
Total administrative expenses before write-off of patents	170,269	131,196
Write-off of patents	50,901	-
	<u>221,170</u>	<u>131,196</u>

The major increase in expenses is due to stock option compensation which is a non-cash expenditure resulting from the issue of stock options to the directors, officers and consultants of the company during the quarter. In addition, a charge of \$51,901 to write-off certain patent applications has been made during the quarter resulting from the decision by the Company to prioritize its research activities on Cancer and Alzheimer's disease, and has discontinued several non priority patent applications during the quarter.

During the six month period ended June 30, 2009, general and administrative expenditures totaled \$308,183 as compared to \$270,802 for the six month period ended June 30, 2008. These expenses are summarized as follows:

	Six months ended June 30,2009 \$	Six months ended June 30,2008 \$
Salaries and wage levies	39,060	86,694
Professional and consulting fees	76,961	64,549
Royalties	5,833	-
Stock option compensation	117,286	88,887
Interest on long-term convertible note	4,502	-
Unrealized gain on foreign exchange	-8,250	-
	<u>235,392</u>	<u>240,130</u>
Other amounts	21,890	30,672
	<u>257,282</u>	<u>270,882</u>
Total administrative expenses before write-off of patents	257,282	270,882
Write-off of patents	50,901	-
	<u>308,183</u>	<u>270,882</u>

The increases in administrative costs were due to the non-cash expenditure of stock option compensation, accrued interest on long-term convertible note payable accrued royalties and the write-off of patents discussed above. These increases were partially offset by the decrease in labour costs and the unrealized gain on foreign exchange. Management has been successful in managing the administrative and overhead costs and is continuously monitoring those costs.

### **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 June 30, 2009, the Company had a net loss of \$284,913 or \$0.0081 per diluted share as compared to a net loss of \$183,048 or \$0.0052 per diluted share for the same period of the previous year.

The current losses reflect certain unusual transactions which can be seen below:

	Three months ended June 30, 2009 \$	Three months ended June 30,2008 \$	Six months ended June 30,2009 \$	Six months ended June 30,2008 \$
Net Loss and Comprehensive income	(284,913)	(183,048)	(420,612)	(369,612)
Loss per share	(0.0081)	(0.0052)	(0.0119)	(0.0104)
Unusual transactions during the period:				
Issue of vested stock options	(92,230)	-	(92,230)	-
Write – off of patents	(50,901)	-	(50,901)	-
Unrealized gain on foreign exchange	14,843	-	8.250	-
Total non-cash unusual transactions	(128,288)	-	(134,881)	-
Effect per share	(0.0036)	-	(0.0038)	-
Loss before unusual non-cash transactions	(156,625)	(183,048)	(285,751)	(369,612)
Loss per share before unusual non-cash transactions	(0.0044)	(0.0052)	(0.0081)	(0.0104)

As indicated earlier, the Company has prioritized its research activities on Cancer and Alzheimer's disease, and has decided to discontinue several non priority patent

applications during the quarter. Accordingly a charge of \$50,901 to write-off those patents has been reflected in the financial statements. The unrealized gain on foreign exchange of \$14,843 was due to the increase in value of the Canadian dollar and its effect on the convertible debt which is repayable in US dollars. As well, the Company issued stock options during the period which were primarily vested and resulted in a non-cash expense of \$92,230 which was included in the total stock option compensation for the quarter of \$103,864.

The Company expects to continue to incur losses as it continues its research and development programs.

### **Working Capital**

As at June 30, 2009 the Company had current assets consisting of cash and cash equivalents, receivables, investment tax credit receivables and prepaid expenses in the aggregate amount of \$756,881 and current liabilities consisting of accounts payable and accrued liabilities of \$189,365, resulting in a working capital of \$567,516 compared to a working capital of \$824,419 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 \$136,000 including interest earned. The balance of the recoverable grant of \$97,106 US Dollars which was to have been receivable upon the ISOA's receipt of a satisfactory initial report of the research, is now receivable once the original balance has been expended.

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, as a result of the current 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 of June 30, 2009, liquid assets totalled \$646,695 or 63.5% of total Company assets; this compares to \$912,352 or 70.6% of total Company assets as at December 31, 2008. As a result, liquid assets have decreased by \$265,657, or 29.1% during the six month period.

As at August 20, 2009, the Company expects that its current capital resources will be sufficient to carry on its overall research and development plans and general operations to February 28, 2010. The ISOA grant funds which is restricted to fund the Alzheimer's research provides the funding for the contract with the PBRC and other related expenses. The contract with PBRC is scheduled to run into September, 2010 and is being funded entirely by the ISOA grant granted to the Company.

The Company will need to obtain new funds in the very near term to continue to pursue its operations. The Company is seeking different strategic alternatives to fund its operations and in spite of the Company's success in obtaining new funds in the past, there is no guarantee of success for the future.

### **RELATED PARTY TRANSACTIONS**

During the three month period ended June 30, 2009, the Company paid a total of \$56,250 to several officers and directors for their services. The amount paid during the six month period ended June 30, 2009 was \$112,500.

### **FINANCIAL INSTRUMENTS**

The Company's financial instruments are comprised of cash and cash equivalents, receivables, accounts payable and accrued liabilities and convertible debt.

## Fair Value

Cash and cash equivalents, receivables and accounts payable and accrued liabilities are all short term in nature and as such, their carrying values approximate fair values.

The company has determined that the convertible debt contains multiple embedded derivatives. The first embedded derivative is a foreign exchange contract which management has determined is not closely related to the host contract, and as such, must be treated separately. The second embedded derivative is the embedded conversion option which requires management to make certain assumptions concerning the market interest rate for a non-convertible debt with similar terms and features. Management has determined that it is unable to measure both the fair value of the embedded foreign exchange contract, as well as determine an appropriate market interest rate in order to bifurcate the debt. As such the entire contract is therefore be treated as a financial liability held for trading. Management has determined that due to the nature of the convertible debt instrument, the Company's inability to obtain any other source of financing and the current financial position of the Company, that it would not be possible to make any meaningful determination of a market interest rate for a non-convertible debt instrument.

## Credit risk

The Company is exposed to credit risk through its cash and its cash equivalents. Credit risk results from the possibility that a loss may occur from the failure of another party to perform according to the terms of a contract. Cash and cash equivalents are maintained with a high quality financial institution. The carrying amount of cash and cash equivalents represents the Company's maximum credit exposure.

## Interest rate risk

The Company manages its portfolio investments based on its cash flow needs and with a view to optimizing its interest income. A change in the interest rates of 1% will not have a significant impact on the operations and cash flows of the Company.

## SUBSEQUENT EVENTS

On July 20, 2009, the Company entered into an agreement to sponsor a research project with Louisiana State University and Agricultural and Mechanical College represented by Pennington Biomedical Research Centre (PBRC). The project cost of \$171,744 USF is funded primarily by the funds received from the ISOA and is to be paid to PBRC based on the achievement of milestones and a set timeline. Funds are expected to be disbursed as follows:

	<u>\$USF</u>
July – September 2009	15,000
October – December 2009	30,000
January 2010 – March 2010	45,000
April 2010 – June 2010	45,000
July 2010 – September 2010	36,744
	<u>171,744</u>

## **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 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 June 30, 2009.

Management has concluded that, as of June 30, 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.