



**OSTA BIOTECHNOLOGIES INC.**

**Management's Discussion and Analysis**

**For the third quarter ended  
September 30, 2007**

## **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 third quarter ended September 30, 2007. It should be read in conjunction with the accompanying unaudited consolidated interim financial statements and related notes for the third quarter ended September 30, 2007 prepared in accordance with Canadian generally accepted accounting principles taking into account material events up to November 20, 2007. 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**

There were no changes in the accounting policies during the period.

## 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	2007	2006	2007	2006
Q1	\$172,835	\$207,318	.0053	.0073
Q2	\$228,104	\$208,850	.0068	.0074
Q3	\$193,008	\$153,234	.0056	.0054
Q4		\$147,590		.0052

### Consolidation of Financial Statements

For the three month period ended September 30, 2007, the financial statements of the Company and Osta are presented on a consolidated basis.

### Outstanding Shares

At September 30, 2007, the Company had 34,706,196 common shares issued and outstanding. Options to acquire an aggregate of 4,245,000 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, 7,228,410 Common Shares have been reserved for issuance pursuant to all outstanding common share purchase 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 nine month period ended September 30, 2007, the Company had revenues of \$30,381 consisting of interest income as compared to \$14,547 for the nine month period ended September 30, 2006. The increase in revenue is due to higher interest rates and management's efforts to manage their cash flow needs.

## **Research and Development Expenses**

The Company had gross expenses during three month period ended September 30, 2007 of \$206,439 as compared to \$156,943 during three month period ended September 30, 2006. During the nine month period ended September 30, 2007, gross expenses were \$624,329 as compared to \$583,948 for the nine month period ended September 30, 2006. The increase in expenses for the three months relate to timing of research costs incurred.

During three month period ended September 30, 2007, the Company spent \$122,523 on research and development (R&D) as compared to \$79,583. During the nine month period ended September 30, 2007, research and development expenses totaled \$376,810 as compared to \$276.665 for the nine month period ended September 30, 2006. The increase in research and development expenses is due mainly to an increase in the research contracts.

## **General & Administrative Expenses**

During the three month period ended September 30, 2007, the Company spent \$61,085 on general and administrative expenses as compared to \$34,422 for the three month period ended September 30, 2006. During the nine month period ended September 30, 2007, general and administrative expenses totaled \$208,048 as compared to \$165,577 for the nine month period ended September 30, 2006. The increase in general and administrative expenses is due mainly to an increase in professional fees and consulting expenses.

## **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 Alzheimer's disease, cancer, XLH, and osteoporosis.

### ***Diagnostic Test for Alzheimer's Disease***

The Company is currently focusing on the development of a novel blood test for Alzheimer's disease (AD). At present, the Company is continuing to advance the clinical studies for the development of its AD blood test and plans to complete these studies in 2008 and pending a successful outcome, the Company will explore the possibility of entering into a co-development and/or licensing agreement for commercialization. The Company's AD test is expected to be classified as a class III In-Vitro Diagnostic Device (IVDD) requiring a Pre-Market Approval ("PMA") filing with FDA anticipated in 2009. Given the low-risk assumed by patients, the Company anticipates that the test will not require an Investigational Device Exemption ("IDE") filing. As such, subject to satisfactory completion of the currently on-going clinical development of its test, the Company intends to license it out to pharmaceutical/diagnostic companies world-wide with a view to initiating its commercialization. If it is successful in this regard, the

Company could begin to generate up-front licensing fees in 2009. The Company expects that it will cost approximately \$500,000 to complete the additional clinical studies required for completing the clinical development of its diagnostic test for AD. At present, the Company is looking to raise additional capital in order to conduct the remaining clinical studies required for the completion of the clinical development of its novel blood test for AD. The future development of this test is heavily dependent on the Company's ability to raise the additional capital in a timely fashion as well as to license out this test to commercial partner(s) for regulatory filing, approvals and commercialization.

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

The Company is developing of a novel therapeutic for the treatment of Alzheimer's disease 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 osteoporosis therapeutic. Upon successful completion of financing in a timely fashion, it plans to complete GLP non-clinical toxicology and safety pharmacology studies in 2010 and plans to file an IND application in 2011 to initiate Phase-I trials in the US. The Company expects that it will cost approximately \$2,000,000 to complete the various pre-clinical studies.

#### ***Cancers Therapeutic Agents***

The Company is developing novel therapeutic agents that could be used as adjuvant chemotherapeutic agents to treat aggressive metastatic, invasive and drug resistant tumors. The Company plans to identify the lead molecule for the treatment of prostate cancer by the end of 2007, complete the pre-clinical studies in 2008 and file an IND application in 2009 to initiate human clinical studies in North America. The Company expects that it will cost approximately \$1,500,000 to complete the various pre-clinical studies.

#### ***Therapeutic Agent for treatment of XLH***

X-Linked Hypophosphatemic rickets (XLH) is a familial form of rickets which results from defects in the PHEX gene. Most cases of XLH, which shows a prevalence of about 1 in 20,000 (Source: [www.athendiagnosics.com](http://www.athendiagnosics.com)), are believed to be associated with X-linked dominant loss-of-function mutations in the gene *PHEX* or autosomal dominant gain-of-function mutation in the gene *FGF23*. No cure exists for XLH, but early initiation of treatment significantly improves the outcome. XLH being a rare disease, the drug for treating XLH could potentially be eligible for an orphan drug status and, therefore, could potentially qualify for an expedited review process with significantly shorter regulatory development time. The Company is developing novel therapeutic agents that could be used to treat XLH. The Company plans to identify the lead molecule for the treatment of XLH by the end of 2008, 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 \$1,500,000 to complete the various pre-clinical studies.

#### ***Osteoporosis Prognostic Test***

The Company is developing a novel prognostic test for assessing the risk of developing low bone mass and osteoporosis. To date, the Company has generated promising results in 264 males and 33 pre-menopausal females. The Company will require additional clinical studies, especially in young males and pre-menopausal females, as well as in multi-race multi-ethnic male and female cohorts prior to licensing out its prognostic test to potential commercial partners and obtaining marketing approval from the FDA. Pending successful completion of additional clinical studies, the Company intends to license out its test to pharmaceutical/diagnostic companies world-wide in 2010. The Company expects that it will cost approximately \$550,000 to complete the clinical studies prior to licensing the test out to potential commercial partners. At present, the Company is looking to raise additional capital in order to conduct the remaining clinical studies required for the completion of the clinical development of its novel prognostic blood test for osteoporosis. The future development of this test is heavily dependent on the Company's ability to raise the additional capital in a timely fashion as well as to license out this test to commercial partner(s) for regulatory filing, approvals and commercialization.

### ***Osteoporosis Therapeutic Agent***

The Company is developing of a novel oral bone forming agent for the treatment of osteoporosis and is at the lead generation stage. The lead molecule(s) will be tested on the Company's proprietary transgenic mouse models to generate a drug candidate which will be taken into pre-clinical and clinical development. The Company needs additional capital to pursue the development of its osteoporosis therapeutic and upon successful completion of financings in a timely fashion, it plans to initiate pre-clinical studies in 2009, with the goal of submitting an IND filing in 2011. The Company expects that it will cost approximately \$2,000,000 to complete the various pre-clinical studies.

### **Results**

For the three month period ended September 30, 2007, the Company had a net loss of \$193,008 or \$0.0056 per share as compared to a net loss of \$153,234 or \$0.0054 per share for the same period of the previous year. In spite of the increase in cost of research the company has been successful in controlling the net loss by the increase in investment income and a decrease in stock option compensation. The Company expects to continue to incur losses as it continues its research and development programs.

### **Working Capital**

As at September 30, 2007, the Company had current assets consisting of cash and cash equivalents, sundry receivables, investment tax credit receivables and prepaid expenses in the aggregate amount of \$1,288,579 and current liabilities consisting of accounts payable and accrued liabilities of \$88,878, resulting in a working capital of \$1,199,701 compared to a working capital of \$1,296,123 as at December 31, 2006. The minor decrease in

working capital is due to the private placement of \$500,000 less the issue costs and the ongoing research and development programs.

### **Liquidity**

The Company believes that the cash at hand at the end of September 30, 2007 is sufficient for conducting the business of the Company for the next 14 months. The company is looking to raise additional capital to fund its various research and development programs as described above.

### **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 blood test for Alzheimer's disease (AD) as well as a novel therapeutic for cancer and XLH. The Company's research and development programs related to the development of novel therapeutic products for Alzheimer's disease & osteoporosis and a novel diagnostic product for osteoporosis are currently on hold 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, cancer and XLH have been advanced significantly. It is estimated that the Company will require approximately \$3.5 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, 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, favourable outcome of regulatory review processes in a timely fashion and other factors that may be beyond the control of Management.

### **RELATED PARTY TRANSACTIONS**

During the three month period ended September 30, 2007, the Company paid a total of \$53,500 to several officers and shareholders for their services. The amount paid during the nine month period ended September 30, 2007 was \$212,900.

## **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 clinical studies for the development of a novel blood test for Alzheimer's disease (AD) and pending successful completion of these studies, the Company anticipates that it would be in a position to potentially establish partnerships with pharmaceutical and/or diagnostic companies for the regulatory approvals and commercialization of the blood test at which stage, the Company is expected to start generating revenues by way of obtaining upfront licensing fees, milestone payments and royalties resulting from the sale of the blood test. In addition, the Company is continuing the development of a novel therapeutic agent for cancer and XLH and expects to initiate pre-clinical toxicology studies in 2008. The Company will require substantial additional capital resources to complete the pre-clinical development of its lead anti-cancer drug and initiate Phase-I clinical studies in North America. 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 2007 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 September 30, 2007.

Management has concluded that, as of September 30, 2007, 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.