



Massachusetts Biologic Laboratories
University of Massachusetts Medical School
305 South Street, Jamaica Plain, MA 02130

Telephone: 617-983-6400 Facsimile: 617-983-9081

October 1, 2007

Honorable Steven T. James
Clerk of the House of Representatives
Room 145
State House
Boston, MA 02133

Honorable William F. Welch
Clerk of the Senate
Room 335
State House
Boston, MA 02133

Dear Mr. James and Mr. Welch:

As required by Chapter 75, Section 43(f), we are pleased to "submit to the Clerks of the Senate and the House of Representatives, a report of the activities of the Biologic Laboratories within ninety days after the end of the fiscal year." This is the eleventh of such annual reports required by the legislation, which transferred the Biologic Laboratories from the Department of Public Health to the University of Massachusetts.

If you have any questions, please contact Dr. Donna Ambrosino, Massachusetts Biologic Laboratories, 305 South Street, Jamaica Plain, MA 02130, (617) 983-6416.

Sincerely,

Michael F. Collins, M.D.
Interim Chancellor
University of Massachusetts Medical School

A handwritten signature in black ink, appearing to read 'Donna M. Ambrosino', written over a horizontal line.

Donna M. Ambrosino, M.D.
Director, Massachusetts Biologic Laboratories
University of Massachusetts Medical School

**A REPORT OF THE ACTIVITIES OF THE BIOLOGIC LABORATORIES
FISCAL YEAR 2007**

AS REQUIRED BY CHAPTER 75, SECTION 43(F)

**SUBMITTED TO
CLERK OF THE HOUSE OF REPRESENTATIVES**

&

CLERK OF THE SENATE

October 1, 2007

BY

**MASSACHUSETTS BIOLOGIC LABORATORIES,
UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL**

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1. INTRODUCTION

This report is submitted, as required by Chapter 75, Section 43(f), on the activities of the Massachusetts Biologic Laboratories, University of Massachusetts Medical School (MBL). This is the eleventh such annual report.

The following sections provide the required information as follows:

Part 2, Prior Fiscal Year (FY07) Information, as indicated by legislation, describes the patents and licenses, agreements entered into, status of existing agreements, royalties and other benefits, and expenditures, current assets and liabilities. This section includes two schedules: (1) FY07 Balance Sheet and (2) FY07 Statement of Revenues and Expenditures and Other Charges. Included here is information related to appropriated funds for the prior fiscal year, as required by the legislation.

Part 3, Financial Plans, presents projected revenues and expenses. A three-year projection is included.

2 PRIOR FISCAL YEAR (FY07) INFORMATION

This section of the report presents the specific information indicated in the legislation related to the prior fiscal year (FY07: July 1, 2006 - June 30, 2007). This is the tenth full year in which the Biologic Laboratories (MBL) has operated within the University of Massachusetts. The effective date of the transfer of the Biologic Laboratories to the University of Massachusetts was January 1, 1997.

a. Patents and Licensing

No new U.S. FDA licenses were approved during FY07.

b. Agreements entered into

There was a three year exclusive distribution agreement entered into in FY07 for the distribution of Tetanus and Diphtheria vaccine with Akorn. *See: Status of existing agreements, royalties and other benefits.*

c. Status of existing agreements, royalties and other benefits

The Biologic Laboratories had the following major existing agreements in FY07.

Medarex - a collaborative development agreement had previously been signed April 17, 2002 with a public company (Medarex). The Biologic Laboratories was to develop and manufacture monoclonal antibody to a target protein in collaboration with Medarex. The agreement is for equal sharing of expenses for the development phase of that project. This agreement was amended in FY06 to include five targets.

The Materials Cooperative Research and Development Agreement (M-CRADA) that was entered into January 30, 2004 with the CDC for Rabies was extended until January 30, 2006. Subsequently, that agreement evolved into a new Inter-institutional Agreement that was executed in August, 2005.

Sale of Reagents: Reagents are by-products of the major manufacturing products of MBL. MBL makes these reagents available for research purposes.

d. Revenues, expenditures, assets and liabilities

On the pages that follow, please find two schedules: (1) FY07 Statement of Revenues and Expenditures and Other Charges, and (2) FY07 Balance Sheet. This information is reviewed as part of the University of Massachusetts annual audit and is included as part of comprehensive financial reports made to the University of Massachusetts' Board of Trustees. Financial activities are also reported to the Office of the State Comptroller.

When reviewing these schedules, please note:

- State Appropriations / DPH represents the DPH appropriated fund support of the effort at the Biologic Laboratories of \$802,685. These funds only partially support staff and provide the supplies and equipment used in the production of vaccines and immune globulin which are distributed to residents of Massachusetts without charge. These products include Tetanus-Diphtheria vaccine (Td), and Immune Globulin used to help prevent outbreaks of Hepatitis A. This is the last year that the Biologic Laboratories will be providing immune globulin as it ceased production in FY06. A thorough process was undertaken to consult DPH, health experts, and FDA so all were prepared for the change.
- License and Royalty Fees represents such payments received for CMV-IGIV, RSV-IGIV and monoclonal RSV antibody.

The Plant Fund is to cover the replacement of major equipment, essential facility improvements necessary to meet FDA and other manufacturing license requirements. This account includes the cumulative capitalized equipment purchases and building improvements and a balance of unexpended funds in reserve for planned equipment purchases and building improvements. In FY07, the plant fund continued to also be used to support the new facility expenses.

The core activities of the Biologic Laboratories will remain consistent through FY08. In calendar year 2007 the Biologic Laboratories submitted its licensure documentation to the FDA to bring its new production facility on line. The Biologic Laboratories expects a favorable outcome from that filing in calendar 2008. The Biologic Laboratories successfully manufactured clinical material in the new facility to support its IND activities.

The new production facility is located at the old Boston State Hospital location. This location was authorized by the legislature in July 2000 and opened October 2005. To support the costs of the new facility, Worcester City Campus Corporation borrowed in FY02 in reliance on its lease with the University of Massachusetts Medical School acting on behalf of the Biologic Laboratories. The plant fund represents payment of the lease payments supporting the bonds, as well as other capital costs associated with Worcester City Campus Corporation, the University of Massachusetts Medical School and the capital needs and operations of the Biologic Laboratories.

Two capital projects were undertaken in 2007; a re-roofing project at the Jamaica Plain campus and additional laboratory and administration facility at Mattapan (Mattapan II). MBL has grown to approximately 370 employees and greatly expanded production as well as research activities. We estimate that the new building at Mattapan will cost \$60 million dollars and be ready to occupy in the summer of 2009. At that time Td manufacturing and support staff will remain at JP with the rest of MBL staff located in Mattapan.

To support the costs of Mattapan II, Worcester City Campus Corporation borrowed \$35 million in FY 07 in reliance on its lease with the University of Massachusetts Medical School acting on behalf of the Biologic Laboratories. The plant fund represents payment of the lease payments supporting the bonds, as well as other capital costs associated with Worcester City Campus Corporation, the University of Massachusetts Medical School and the capital needs and operations of the Biologic Laboratories.

The projected amount of funds appropriated from the interdepartmental service agreement with the DPH for the next three years would be approximately the same as FY07 with the addition of collective bargaining increases and associated fringe benefits adjustments for the staff supported by these funds, unless state requirements for products and services were to increase. The FY08 approximate appropriation is \$802,685.

e.

University of Massachusetts Biologic Laboratories
Statement of Revenues, Expenditures and Other Changes
For the Period July 1, 2006 Through June 30, 2007
(Unaudited)

	<u>CURRENT FUND</u>	<u>APPROPRIATED FUNDS</u>	<u>TOTAL</u>
REVENUE AND OTHER ADDITIONS:			
Product Sales	58,222,525		58,222,525
Restricted Grants & Contracts	266,553		266,553
State Appropriations/DPH		802,685	802,685
Royalty Fees and Interest	33,689,823		33,689,823
Recovery of Indirect Cost	221,024		221,024
	<hr/>	<hr/>	<hr/>
Total Revenue and Other Additions	<u>92,399,925</u>	<u>802,685</u>	<u>93,202,610</u>
EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	21,024,338	423,212	21,447,550
Fringe Benefits	5,514,348	115,111	5,629,459
Supplies and Services	48,453,853	264,362	48,718,215
	<hr/>	<hr/>	<hr/>
Total Expenditures and Other Deductions	<u>74,992,539</u>	<u>802,685</u>	<u>75,795,224</u>
Net Increase/(Decrease) Before Transfers	17,407,386	-	17,407,386
Nonmandatory Transfers			
Transfer - Plant Fund	(9,085,487)		(9,085,487)
Transfer - equipment to plant	(2,759,534)		(2,759,534)
	<hr/>	<hr/>	<hr/>
Total Transfers	<u>(11,845,021)</u>	<u>0</u>	<u>(11,845,021)</u>
Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			0
NET INCREASE(DECREASE) FOR THE YEAR	5,562,365	0	5,562,365
Fund Balances at Beginning of Year (7/1/06)	<u>64,820,704</u>	<u>0</u>	<u>64,820,704</u>
FUND BALANCES AT END OF YEAR	<u>70,383,070</u>	<u>0</u>	<u>70,383,070</u>

f.

University of Massachusetts Biologic Laboratories

Balance Sheet

As of June 30, 2007

(Unaudited)

	CURRENT FUND FY07	PLANT FUND FY07	TOTAL FY07
Assets			
Cash	47,423,894	12,515,993	59,939,887
Accounts Receivable	19,858,974		19,858,974
Inventory	6,298,420		6,298,420
Prepaid Expenses	91,657		91,657
Buildings & Equipment		12,526,325	12,526,325
Total Assets	73,672,944	25,042,318	98,715,263
Liabilities			
Accounts Payable	2,891,536	35,298	2,926,834
Employee-Related Accruals	392,756		392,756
Other Liabilities	5,582		5,582
Total Liabilities	3,289,875	35,298	3,325,172
Fund Balances	70,383,070	25,007,021	95,390,090
Total Liabilities and Fund Balance	<u>\$73,672,944</u>	<u>\$25,042,318</u>	<u>\$98,715,263</u>
Debt Balance		\$101,745,000	\$101,745,000

FINANCIAL PLANS

University of Massachusetts Biologic Laboratories
Statement of Revenues, Expenditures and Other Changes
For the Period July 1, 2007 Through June 30, 2008
(Unaudited)

	<u>CURRENT FUND</u>	<u>APPROPRIATED FUNDS</u>	<u>TOTAL</u>
REVENUE AND OTHER ADDITIONS:			
Product Sales	37,190,000		37,190,000
Restricted Grants & Contracts			
State Appropriations/DPH		802,685	802,685
Royalty Fees and Interest	27,705,898		27,705,898
Recovery of Indirect Cost			
Total Revenue and Other Additions	64,895,898	802,685	65,698,583
EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	24,849,509	423,212	25,272,721
Fringe Benefits	7,176,069	115,111	7,291,180
Supplies and Services	22,411,435	264,362	22,675,797
Total Expenditures and Other Deductions	54,437,013	802,685	55,239,698
Net Increase/(Decrease) Before Transfers	10,458,885	0	10,458,885
Nonmandatory Transfers			
Transfer - Plant Fund	(12,000,000)		(12,000,000)
Transfer - equipment to plant	(2,321,329)		(2,321,329)
Total Transfers	(14,321,329)	0	(14,321,329)
Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			
NET INCREASE(DECREASE) FOR THE YEAR	(3,862,444)	0	(3,862,444)
Fund Balances at Beginning of Year (7/1/07)	70,383,070	0	70,383,070
FUND BALANCES AT END OF YEAR	66,520,626	0	66,520,626

University of Massachusetts Biologic Laboratories
Statement of Revenues, Expenditures and Other Changes
For the Period July 1, 2008 Through June 30, 2009
(Unaudited)

	<u>CURRENT FUND</u>	<u>APPROPRIATED FUNDS</u>	<u>TOTAL</u>
REVENUE AND OTHER ADDITIONS:			
Product Sales	46,340,000		46,340,000
Restricted Grants & Contracts			0
State Appropriations/DPH		802,685	802,685
Royalty Fees and Interest	29,242,370		29,242,370
Recovery of Indirect Cost			0
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Total Revenue and Other Additions	<u>75,582,370</u>	<u>802,685</u>	<u>76,385,055-</u>
EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	26,833,886	423,212	27,257,098
Fringe Benefits	7,748,562	115,111	7,863,673
Supplies and Services	35,406,448	264,362	35,670,810
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Total Expenditures and Other Deductions	<u>69,988,895</u>	<u>802,685</u>	<u>70,791,580</u>
Net Increase/(Decrease) Before Transfers	5,593,475	0	5,593,475
Nonmandatory Transfers			
Transfer - Plant Fund	(35,000,000)		(35,000,000)
Transfer - equipment to plant	(2,402,576)		(2,402,576)
	<hr/>	<hr/>	<hr/>
Total Transfers	<u>(37,402,576)</u>	<u>0</u>	<u>(37,402,576)</u>
Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			0
NET INCREASE(DECREASE) FOR THE YEAR	(31,809,101)	0	(31,809,101)
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Fund Balances at Beginning of Year (7/1/08)	<u>66,520,626</u>	<u>0</u>	<u>66,520,626</u>
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FUND BALANCES AT END OF YEAR	<u>34,711,525</u>	<u>0</u>	<u>34,711,525</u>

University of Massachusetts Biologic Laboratories
Statement of Revenues, Expenditures and Other Changes
For the Period July 1, 2009 Through June 30, 2010
(Unaudited)

	CURRENT FUND	APPROPRIATED FUNDS	TOTAL
REVENUE AND OTHER ADDITIONS:			
Product Sales	57,540,000		57,540,000
Restricted Grants & Contracts			0
State Appropriations/DPH		802,685	802,685
Royalty Fees and Interest	30,941,760		30,941,760
Recovery of Indirect Cost			0
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Total Revenue and Other Additions	88,481,760	802,685	89,284,445
EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	28,502,688	423,212	28,925,900
Fringe Benefits	8,230,011	115,111	8,345,122
Supplies and Services	39,754,182	264,362	40,018,544
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Total Expenditures and Other Deductions	76,486,881	802,685	77,289,566
Net Increase/(Decrease) Before Transfers	11,994,879	0	11,994,879
Nonmandatory Transfers			
Transfer - Plant Fund	(19,000,000)		(19,000,000)
Transfer - equipment to plant	(2,486,666)		(2,486,666)
	<hr/>	<hr/>	<hr/>
Total Transfers	(21,486,666)	0	(21,486,666)
Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			0
NET INCREASE(DECREASE) FOR THE YEAR	(9,491,787)	0	(9,491,787)
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Fund Balances at Beginning of Year (7/1/09)	34,711,525	0	34,711,525
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FUND BALANCES AT END OF YEAR	25,219,738	0	25,219,738