



**Massachusetts Biologic Laboratories**  
**University of Massachusetts Medical School**  
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October 1, 2001

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

Honorable Patrick F. Scanlan  
Clerk of the Senate  
Room 335  
State House  
Boston, MA 02133

Dear Mr. Scanlan and Mr. James:

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 fifth 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, University of Massachusetts Biologic Laboratories, 305 South Street, Jamaica Plain, MA 02130, (617) 983-6416.

Sincerely,

Aaron Lazare, M.D.  
Chancellor/Dean  
University of Massachusetts Medical School

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

M 1001

**A REPORT OF THE ACTIVITIES OF THE BIOLOGIC LABORATORIES  
FISCAL YEAR 2001**

**AS REQUIRED BY CHAPTER 75, SECTION 43(F)**

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

**&**

**CLERK OF THE SENATE**

**OCTOBER 1, 2001**

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

**TABLE OF CONTENTS**

**1. INTRODUCTION ..... 3**

**2. PRIOR FISCAL YEAR (FY01) INFORMATION ..... 4**

    a. Patents and Licensing ..... 4

    b. Agreements entered into ..... 4

    c. Status of existing agreements, royalties and other benefits ..... 4

    d. Revenues, expenditures, assets and liabilities ..... 5

    e. FY01 Statement of Revenues, Expenditures and Other Changes ..... 7

    f. FY01 Balance Sheet ..... 8

**3. FINANCIAL PLANS ..... 9**

    a. FY02 Projected Statement of Revenues, Expenditures and Other Changes ..... 10

## **1. INTRODUCTION**

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

The following sections provide the required information as follows:

Part 2, Prior Fiscal Year (FY01) 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) FY01 Balance Sheet and (2) FY01 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 notation regarding the "projections of the amount of appropriated funds required for the next three years" is included here.

## 2. PRIOR FISCAL YEAR (FY01) INFORMATION

This section of the report presents the specific information indicated in the legislation related to the prior fiscal year (FY01: July 1, 2000- June 30, 2001). This is the fourth 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

There were no new patents received by the Biologic Laboratories during FY01. No new U.S. FDA licenses were approved during FY01.

### b. Agreements entered into

There was one new agreement consummated in FY01.

Sunol - a collaborative development was signed July 24, 2001 with private company (Sunol Molecular Corporation). The Biologic Laboratories is to develop and manufacture monoclonal antibody to a target protein (tissue factor) in collaboration with Sunol. The initial agreement was for \$967,217 to be complete by August 31, 2001 upon delivery of material for clinical studies.

### c. Status of existing agreements, royalties and other benefits

The Biologic Laboratories had the following major existing agreements in FY01. The understandings and relationships between the Biologic Laboratories, Massachusetts Health Research Institute (MHRI) and MedImmune, Inc. regarding Respiratory Syncytial Virus Immune Globulin, Intravenous (RSV-IGIV) and Cytomegalovirus Immune Globulin, Intravenous (CMV-IGIV) have been resolved. An amendment to the RSV-IGIV agreement was signed to allow MedImmune to distribute the monoclonal antibody "Synagis™" to at-risk infants in Maine and Massachusetts. MBL is preparing to manufacture and seek licensure for this product in the future.

American Red Cross, Northeast Region - Plasma Fractionation: This is renewed on an annual basis for the development and manufacture of special Immune Globulins and other plasma derivatives. The Biologic Laboratories manufactures products such as Varicella Zoster Immune Globulin (VZIG), Immune Globulin (IG) and Albumin using materials supplied by the Red Cross, which the Red Cross then distributes.

New York Blood Center - IGIV Technology: This is a licensing agreement, whereby the Biologic Laboratories' proprietary method to prepare Immune Globulin products that can be administered intravenously (IGIV) was licensed by the New York Blood Center in 1990. The Biologic Laboratories receives a three percent royalty of gross sales.

U.S. Agency for International Development (USAID) - International Training Program: This is a five year (9/25/95 - 9/24/00) grant totaling \$1,926,490 to train scientists from developing countries in quality control and Good Manufacturing Practices (GMP) for the manufacture of vaccines in their countries. This grant was recently extended to 9/24/02.

National Institutes of Health (NIH) - Vaccine Production Facility for New Vaccines: This is a five-year contract (9/30/96 - 9/29/01) totaling approximately \$5 million for the development of vaccines and monoclonal antibodies for new and emerging diseases. This has been extended to 9/29/02.

Swiss Serum and Vaccine Institute - HibT Vaccine: The Biologic Laboratories entered into a collaborative research and development agreement with the Swiss Serum and Vaccine Institute (SSVI) to develop a vaccine against *Haemophilus influenzae* type b (HibT). The HibT vaccine development has been suspended.

Swiss Serum and Vaccine Institute - Acellular Pertussis Vaccine: The Biologic Laboratories also entered into a collaborative agreement with SSVI for the development of an acellular pertussis vaccine. Work on this vaccine has been suspended.

DynPort: This is a subcontract to DynPort for a contract with the U.S. Department of Defense to manufacture small pox globulin developed for research and in preparation for a bioterrorist attack. ~~A total of 4 lots will be manufactured and complete in FY02.~~ ~~NOT CORRECT~~

<sup>One or more lots</sup> Sale of Reagents: Reagents are by-products of the major manufacturing products of the Biologic Laboratories. The Biologic Laboratories makes these reagents available for research purposes.

Inhibitex--contract to manufacture one lot of hyperimmune globulin for clinical trials in FY00 (\$456,621). No additional lots are planned at this time.

California Department of Public Health - Botulism Immune Globulin: The Biologic Laboratories entered into a new manufacturing agreement with the California Dept of Health Services (CDHS) for manufacture of Botulism Immune Globulin (BIG) in FY00. The product is currently being distributed under a Treatment IND by CDHS. <sup>CDHS is planning to apply</sup> ~~CDHS is planning to apply~~ for a full FDA license in FY02. As previously noted, CDHS completed a Phase III study FY97 which showed that BIG was very effective in treating infant botulism. MBL manufactured a new lot in support of California's seeking licensure for this product for \$477,106.

d. Revenues, expenditures, assets and liabilities

On the pages that follow, please find two schedules: (1) FY01 Statement of Revenues and Expenditures and Other Charges, and (2) FY01 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 \$789,326. These funds help support staff and associated supplies and equipment used in the production of vaccines, immune globulins and other products which are distributed to residents of Massachusetts without charge. These products include Tetanus-Diphtheria vaccine (Td), Varicella Zoster Immune Globulin (VZIG) given to children with severe underlying illnesses such as leukemia or AIDS who are exposed to chickenpox, and Immune Globulin used to help prevent outbreaks of Hepatitis A.
- License and Royalty Fees represents such payments received for CMV-IGIV, from the New York Blood Center, for RSV-IGIV and monoclonal RSV antibody (SynGene).
- 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.

and additions?



University of Massachusetts Biologic Laboratories  
 Statement of Revenues, Expenditures and Other Changes  
 For the Period July 1, 2000 Through June 30, 2001  
 (Unaudited)

	CURRENT FUND	APPROPRIATED FUNDS	TOTAL
<b>REVENUE AND OTHER ADDITIONS:</b>			
Product Sales	12,774,860		12,774,860
Restricted Grants & Contracts	564,770		564,770
State Appropriations/DPH		789,326	789,326
Royalty Fees and Interest	12,058,192		12,058,192
Recovery of Indirect Cost	(34,195)		(34,195)
Other Income	9,879		9,879
<b>Total Revenue and Other Additions</b>	<b>25,373,506</b>	<b>789,326</b>	<b>26,162,832</b>
<b>EXPENDITURES AND OTHER DEDUCTIONS:</b>			
Salaries	7,831,629	412,656	8,244,285
Fringe Benefits	2,075,158	119,670	2,194,828
Supplies and Services	10,142,135	257,000	10,399,135
<b>Total Expenditures and Other Deductions</b>	<b>20,048,922</b>	<b>789,326</b>	<b>20,838,248</b>
<b>Net Increase/(Decrease) Before Transfers</b>	<b>5,324,584</b>	<b>0</b>	<b>5,324,584</b>
<b>Nonmandatory Transfers</b>			
Transfer - Plant Fund	(2,470,782)		(2,470,782)
<b>Total Transfers</b>	<b>(2,470,782)</b>	<b>0</b>	<b>(2,470,782)</b>
<b>Other Changes</b>			
Excess of Restricted Receipts over Transfers to Reve	(152,710)	0	(152,710)
<b>NET INCREASE(DECREASE) FOR THE YEAR</b>	<b>2,701,092</b>	<b>0</b>	<b>2,701,092</b>
<b>Fund Balances at Beginning of Year (7/1/00)</b>	<b>20,306,105</b>	<b>0</b>	<b>20,306,105</b>
<b>FUND BALANCES AT END OF YEAR</b>	<b>23,007,197</b>	<b>0</b>	<b>23,007,197</b>

M 1008



University of Massachusetts Biologic Laboratories  
 f. Balance Sheet  
 As of June 30, 2001  
 (Unaudited)

	CURRENT FUND	PLANT FUND	TOTAL
<b>ASSETS:</b>			
Cash	13,922,267	7,815,137	21,737,404
Employee Travel			0
Account Receivable	9,558,130		9,558,130
Prepaid Insurance			0
Inventory	1,499,170		1,499,170
Buildings & Equipment		13,409,555	13,409,555
	<hr/>	<hr/>	<hr/>
<b>TOTAL ASSETS</b>	<u>24,979,567</u>	<u>21,224,692</u>	<u>46,204,259</u>
<b>LIABILITIES:</b>			
Accounts Payable	496,203		496,203
Employee-Related Accruals	695,551		695,551
Other Liabilities	780,615		780,615
	<hr/>	<hr/>	<hr/>
<b>TOTAL LIABILITIES</b>	<u>1,972,369</u>	<u>0</u>	<u>1,972,369</u>
<b>FUND BALANCES:</b>			
	<hr/>	<hr/>	<hr/>
<b>TOTAL FUND BALANCES</b>	<u>23,007,198</u>	<u>21,224,692</u>	<u>44,231,890</u>
<b>TOTAL LIABILITIES AND FUND BALANCES</b>	<u>24,979,567</u>	<u>21,224,692</u>	<u>46,204,259</u>

### 3. FINANCIAL PLANS

The Biologic Laboratories' one-year financial plan is represented by the attached FY01 Statement of Revenues and Expenditures and Other Changes. In July 2000, the legislature authorized the use of land for facility expansion at the old Boston State Hospital location. We will now complete planning for that project and file a report with long term projections at the time we complete the lease transaction.

The projected amount of appropriated funds for the next three years would be approximately the same as FY01 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 FY01 appropriation is, therefore, \$789,326.

*Did we inc for this? I don't think so. Maybe we should!*

Although we are not submitting a long term financial plan, we are able to identify expenses in the coming years. One extraordinary expense will be related to facility improvements. The physical plant is over-crowded and must be modernized and expanded to meet the increasing regulatory requirements of the FDA and to provide opportunities for new product development. The long term survival of this facility is dependent upon these improvements. While only anticipated to be a partial source of funds, the Plant Fund has been established in order to assist with the financing of major capital projects and equipment purchases. The substantial fund balances will be needed to offset these large future anticipated expenses, including the proposed new building (aseptic filling suite and new monoclonal antibody production units).

Several major multi-million dollar capital projects are anticipated at this time:

- The aseptic filling and packaging facility is a core operation for all MBL's products. The current area is too small to handle the growing product line. New technology is required to meet the increasing regulatory requirements of the FDA. We are planning on locating this function at the former Boston State Hospital property, as indicated in the legislation authorizing the Biologic Laboratories' use of the land. The financial impact of this will be further identified in the interim report to be filed when the lease transaction is complete.
- Addition to the laboratories dedicated to the development of novel vaccines and monoclonal antibodies. The Biologic Laboratories' newest contract with the National Institutes for Health requires the development of novel monoclonal antibodies (MAb). MBL has produced one MAb being studied this year in AIDS patients with life-threatening fungal infections. In addition, two monoclonal antibodies have been manufactured to be used in children exposed to *E. coli* 0157 ("hamburger disease") to prevent the development of life-threatening kidney failure. Finally, one new product (Tissue Factor MAb) is being collaboratively developed. Development and production of these new products require production areas with stringent environmental specifications for cleanroom operations (per FDA regulations). The existing laboratories are being renovated to accommodate these needs and the new facility will also have manufacturing capacity for MAbs.

University of Massachusetts Biologic Laboratories  
a. Statement of Revenues, Expenditures and Other Changes  
Forecast for the Period July 1, 2001 Through June 30, 2002

	CURRENT FUND	APPROPRIATED FUNDS	TOTAL
<b>REVENUE AND OTHER ADDITIONS:</b>			
Product Sales	15,005,820		15,005,820
Restricted Grants & Contracts	2,244,600		2,244,600
State Appropriations/DPH		789,068	789,068
License and Royalty Fees	12,212,314		12,212,314
Recovery of Indirect Cost	716,082		716,082
	<u>30,178,816</u>	<u>789,068</u>	<u>30,967,884</u>
<b>EXPENDITURES AND OTHER DEDUCTIONS:</b>			
Salaries	10,498,291	412,456	10,910,747
Fringe Benefits	3,044,504	119,612	3,164,116
Supplies and Services	8,742,524	257,000	8,999,524
	<u>22,285,319</u>	<u>789,068</u>	<u>23,074,387</u>
<b>Total Expenditures and Other Deductions</b>			
<b>Net Increase/(Decrease) Before Transfers</b>	7,893,497	0	7,893,497
<b>Nonmandatory Transfers</b>			
Transfer - Plant Fund	(2,151,100)		(2,151,100)
	<u>(2,151,100)</u>	<u>0</u>	<u>(2,151,100)</u>
<b>Total Transfers</b>			
<b>Other Changes</b>			
Excess of Restricted Receipts over Transfers to Revenue		0	0
<b>NET INCREASE(DECREASE) FOR THE YEAR</b>	5,742,397	0	5,742,397
<b>Fund Balances at Beginning of Year (7/1/01)</b>	<u>23,007,197</u>	<u>0</u>	<u>23,007,197</u>
<b>FUND BALANCES AT END OF YEAR</b>	<u>28,749,594</u>	<u>0</u>	<u>28,749,594</u>

M 1011