



UMass Chan
MEDICAL SCHOOL

MassBiologics Medicine for Better

October 1, 2024

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

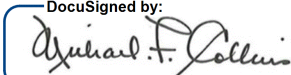
Honorable Michael D. Hurley
Clerk of the Senate
Room 335
State House
Boston, MA 02133

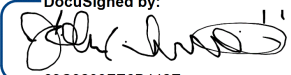
Dear Mr. James and Mr. Hurley:

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 University of Massachusetts laboratories within ninety days after the end of the fiscal year.” This is the twenty-seventh year of such annual report required by the legislation, which transitioned the biologic laboratories of the state laboratory institute from the Department of Public Health to the University of Massachusetts.

If you have any questions, please contact Executive Vice Chancellor John C. Lindstedt, UMass Chan Medical School, 55 Lake Ave. North, Worcester, MA 01655, (508) 856-2198.

Sincerely,

DocuSigned by:

38FA3D35965846D...
Michael F. Collins, M.D.
Chancellor
University of Massachusetts Chan Medical School

DocuSigned by:

63C209FE6B442E...
John C. Lindstedt
Executive Vice Chancellor, A&F
University of Massachusetts Chan Medical School

**A REPORT OF THE ACTIVITIES OF MASSBIOLOGICS
FISCAL YEAR 2024**

AS REQUIRED BY CHAPTER 75, SECTION 43(F)

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

&

CLERK OF THE SENATE

October 1, 2024

BY

**MASSBIOLOGICS of the
UNIVERSITY OF MASSACHUSETTS CHAN 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 MassBiologics of the University of Massachusetts Chan Medical School. This is the twenty-seventh year of such annual report.

The following sections provide the required information as follows:

Part 2, Prior Fiscal Year (FY24) 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) FY24 Statement of Revenues and Expenditures and Other Changes and (2) FY24 Balance Sheet. 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 (FY24) INFORMATION

This section of the report presents the specific information indicated in the legislation related to the prior fiscal year (FY24: July 1, 2023 - June 30, 2024). This is the twenty-seventh full year in which MassBiologics has operated within the University of Massachusetts. The effective date of the transfer to the University of Massachusetts was January 1, 1997.

a. Patents and Licensing

MassBiologics had two patents issued in FY24:

- 1) Anti-ETEC Adhesin Protein Antibodies and Methods of Use
8/22/2023 United States Patent Number 11732032
- 2) Anti-CfaE Antibodies and Methods of Use
11/28/2023 United States Patent Number 11827670

b. Collaboration and CDMO Service Agreements entered into:

MassBiologics Contract Development and Manufacturing Services in FY24 include:

- 1) Four existing clients continuing their production programs.
- 2) Eleven new project specific service agreements were executed in FY24. Total CDMO revenue recognized in FY24 was \$18M

c. Status of existing agreements, royalties and other benefits / challenges

MassBiologics had the following major existing agreements in FY24.

Medimmune (formerly Molecular Vaccines), license for Synagis, a therapeutic for Respiratory Syncytial Virus (RSV) signed August 1, 1989. Medimmune is a wholly owned subsidiary of AstraZeneca Pharmaceuticals, and divested US rights to Synagis to Swedish Orphan Biovitrum (Sobi) in January 2019. We are aware of several competing products now on the market that also treat RSV, and accordingly, we are monitoring the potential impact of these competing products on our future royalty revenues from Synagis sales.

Medimmune (formerly Molecular Vaccines), license for CytoGam, a therapeutic for Cytomegalo Virus signed April 23, 1990. Medimmune sold CytoGam rights to ZLB Behring (part of CSL Behring) November 8, 2006. Saol Therapeutics acquired CytoGam rights from CSL Behring August 6, 2019.

Bristol-Meyers Squibb, formerly Medarex has a Collaborative Development Agreement signed April 17, 2002 with a public company (Medarex) and has led to discovery of several antibodies. Commercial licenses are in place that grant MassBiologics commercialization rights to these antibodies, including the treatment of Rabies, *C. difficile*, Lyme, and ETEC.

A Materials Cooperative Research and Development Agreement (M-CRADA) was entered on January 30, 2004 with the CDC for Rabies and then extended until January 30, 2006. Subsequently, that agreement evolved into an Inter-Institutional Agreement which was executed in August 2005.

Merck Exclusive License Agreement was signed April 20, 2009 for antibodies against *C. difficile*. This agreement remains in place and support of commercialization of MassBiologics' proprietary *C. difficile* antibodies.

Serum Institute of India License and Collaboration Agreement was effective September 27, 2006. This agreement remains in effect for the development and commercialization of a Rabies Monoclonal Antibody for the treatment of Rabies.

Grifols Inc. Distribution Agreement effective July 1, 2015 is for Tetanus Diphtheria Vaccine (Td) in USA, Canada and Europe under the TDVAX tradename. This agreement was terminated in 2024 and will be excluded from subsequent annual reports. With respect to same, we have consulted with the Commonwealth's Department of Public Health with respect to ceasing Td manufacturing due to the widespread use of the more effective Tdap vaccine, and the DPH advised that they, too, are moving to the Tdap product because of that drug's advantages and at an overall cost savings.

Beginning with the onset of the Covid-19 pandemic and continuing through this FY24, we have been studying the long-term sustainability and financial challenges of the MassBiologics manufacturing operations, as now similarly experienced by other biomanufacturing businesses in the Commonwealth, and in response to same, we have engaged outside consultants, including William Blair and TKD Solutions, to assist us in better understanding the current marketplace and developing a new strategic plan for same.

Commencing in FY24 and continuing into this FY25, our MassBiologics and UMass Chan facilities, in Mattapan and Fall River, respectively, underwent certain regulatory inspections – we expect to receive the final results of these inspections in FY25, at which point, we will consider the impact of same on the existing manufacturing operations.

During this FY24, we have taken certain staff actions and utilized the services of consultants to ensure we are able to fulfil our current contractual obligations.

As referenced in the Land Disposition Agreements attendant to the development and construction of the two (2) MassBiologics buildings in Mattapan, we regularly met with the local Citizens Advisory Committee and fully met all financial obligations related to same.

d. Revenues, expenditures, assets and liabilities

On the pages that follow, please find two schedules: (1) FY24 Statement of Revenues and Expenditures and Other Charges and (2) FY24 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:

- License and Royalty Fees represents such payments received for CMV-IGIV, and monoclonal antibodies to RSV, Rabies and *C. difficile*.

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.

The core activities of MassBiologics remained consistent through FY24. In calendar year 2008, MassBiologics received its licensure from the FDA to bring its new production facility on line. MassBiologics continued to manufacture clinical material in the new facility to support its IND activities.

The 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 facility, Worcester City Campus Corporation borrowed in FY02 in reliance on its lease with the University of Massachusetts Chan Medical School acting on behalf of MassBiologics. 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 Chan Medical School and the capital needs and operations of MassBiologics.

Construction of Mattapan II was completed in the late spring of 2010. The project was on time and within budget. Mattapan II was also occupied in this timeframe.

To support the costs of Mattapan II, Worcester City Campus Corporation borrowed \$35M in FY07 in reliance on its lease with the University of Massachusetts Chan Medical School acting on behalf of MassBiologics.

It was determined that MassBiologics would benefit from consolidating its operations to one campus by making facilities modifications to the Mattapan Campus. Modifications completed by June 2013 made it possible for MassBiologics to leave the Jamaica Plain Campus effective June 30, ending a 119 year tenancy at that campus. Commissioning and validation activities have been completed and the FDA has inspected and approved the manufacturing of Tetanus Diphtheria Vaccine (Td).

In FY15, the University of Massachusetts President's Office determined that the previously constructed Massachusetts Accelerator for Biomanufacturing (MAB) facility (located at 1240 Innovation Way in Fall River, MA), developed under the guidance of the UMASS Dartmouth campus would be a better strategic fit if it were configured as a cGMP manufacturing resource for the development of vectored therapeutics under the operational control of UMass Chan Medical School (UMass Chan). Grants totaling \$10M from the MLSC and MassWorks were invested in the facility to support the cGMP requirements of vector manufacturing. In FY16, the initial scope of work was completed on time and on budget with a few areas identified for future projects and validation is ongoing.

UMass Chan received a \$2M business loan from the Greater Fall River Development in FY16. Payments were repaid over five years, with the last payment in July 2020.

In FY17, the outstanding bonds related to the facilities discussed were refinanced, thereby reducing the future debt service payments.

**University of Massachusetts Biologic Laboratories
Statement of Revenues, Expenditures and Other Changes
For the Period July 1, 2023 through June 30, 2024
(Unaudited)**

	<u>CURRENT FUND</u>	<u>APPROPRIATED FUNDS</u>	<u>TOTAL</u>
REVENUE AND OTHER ADDITIONS:			
Product Sales	23,014,621	0	23,014,621
Royalty Fees and Interest	17,062,316	0	17,062,316
Other Income	497,855	0	497,855
	<hr/>		
Total Revenue and Other Additions	40,574,792	0	40,574,792
EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	11,914,707	0	11,914,707
Fringe Benefits	3,583,011	0	3,583,011
Supplies and Services	30,679,734	0	30,679,734
Depreciation	1,849,346	0	1,849,346
	<hr/>		
Total Expenditures and Other Deductions	48,026,798	0	48,026,798
Net Increase/(Decrease) Before Transfers	(7,452,006)	0	(7,452,006)
Nonmandatory Transfers			
Transfers	(482,858)	0	(482,858)
	<hr/>		
Total Transfers	(482,858)	0	(482,858)
Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			
NET INCREASE(DECREASE) FOR THE YEAR	(7,934,865)	0	(7,934,865)
Fund Balances at Beginning of Year (7/1/23)	18,622,727	0	18,622,727
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FUND BALANCES AT END OF YEAR	10,687,863	0	10,687,863

University of Massachusetts Biologic Laboratories
Balance Sheet
As of June 30, 2024
(Unaudited)

	CURRENT FUND FY24	PLANT FUND FY24	TOTAL FY24
Assets			
Cash	4,681,827	0	4,681,827
Accounts Receivable	8,698,795	0	8,698,795
Prepaid Expenses	6,375,166	0	6,375,166
Buildings & Equipment	0	9,719,605	9,719,605
Total Assets	19,755,788	9,719,605	29,475,393
Liabilities			
Accounts Payable	2,438,911	0	2,438,911
Employee-Related Accruals	361,173	0	361,173
Other Liabilities	15,987,446	0	15,987,446
Total Liabilities	18,787,531	0	18,787,531
Fund Balances	968,258	9,719,605	10,687,863
Total Liabilities and Fund Balance	19,755,788	9,719,605	29,475,393

Financial Plans

**University of Massachusetts Biologic Laboratories
Statement of Revenues, Expenditures and Other Changes
For the Period July 1, 2024 Through June 30, 2025
(Unaudited)**

	<u>CURRENT FUND</u>	<u>APPROPRIATED FUNDS</u>	<u>TOTAL</u>
REVENUE AND OTHER ADDITIONS:			
Product Sales	13,534,794	0	13,534,794
Royalty Fees and Interest	15,900,554	0	15,900,554
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Total Revenue and Other Additions	29,435,348	0	29,435,348
EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	8,451,051	0	8,451,051
Fringe Benefits	2,050,000	0	2,050,000
Supplies and Services	22,222,192	0	22,222,192
Depreciation	1,883,555	0	1,883,555
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Total Expenditures and Other Deductions	34,606,798	0	34,606,798
Net Increase/(Decrease) Before Transfers	(5,171,450)	0	(5,171,450)
Nonmandatory Transfers			
Transfers	0	0	0
	<hr/>		
Total Transfers	0	0	0
Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			
NET INCREASE(DECREASE) FOR THE YEAR	(5,171,450)	0	(5,171,450)
Fund Balances at Beginning of Year (7/1/25)	10,687,863	0	10,687,863
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FUND BALANCES AT END OF YEAR	5,516,413	0	5,516,413

University of Massachusetts Biologic Laboratories
Statement of Revenues, Expenditures and Other Changes
For the Period July 1, 2028 Through June 30, 2026
(Unaudited)

	<u>CURRENT FUND</u>	<u>APPROPRIATED FUNDS</u>	<u>TOTAL</u>
REVENUE AND OTHER ADDITIONS:			
Product Sales	13,940,837	0	13,940,837
Royalty Fees and Interest	16,377,571	0	16,377,571
Other Income	0	0	0
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Total Revenue and Other Additions	30,318,408	0	30,318,408
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EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	8,704,583	0	8,704,583
Fringe Benefits	2,111,500	0	2,111,500
Supplies and Services	22,888,858	0	22,888,858
Depreciation	1,940,062	0	1,940,062
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Total Expenditures and Other Deductions	35,645,002	0	35,645,002
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Net Increase/(Decrease) Before Transfers	(5,326,594)	0	(5,326,594)
Nonmandatory Transfers			
Transfers	0	0	0
	<hr/>		
Total Transfers	0	0	0
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Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			
NET INCREASE(DECREASE) FOR THE YEAR	(5,326,594)	0	(5,326,594)
Fund Balances at Beginning of Year (7/1/26)	5,516,413	0	5,516,413
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FUND BALANCES AT END OF YEAR	189,819	0	189,819
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University of Massachusetts Biologic Laboratories
Statement of Revenues, Expenditures and Other Changes
For the Period July 1, 2026 Through June 30, 2027
(Unaudited)

	<u>CURRENT FUND</u>	<u>APPROPRIATED FUNDS</u>	<u>TOTAL</u>
REVENUE AND OTHER ADDITIONS:			
Product Sales	14,359,062	0	14,359,062
Royalty Fees and Interest	16,868,898	0	16,868,898
Other Income	0	0	0
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Total Revenue and Other Additions	31,227,960	0	31,227,960
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EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	8,965,720	0	8,965,720
Fringe Benefits	2,174,845	0	2,174,845
Supplies and Services	23,575,523	0	23,575,523
Depreciation	1,998,263	0	1,998,263
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Total Expenditures and Other Deductions	36,714,352	0	36,714,352
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Net Increase/(Decrease) Before Transfers	(5,486,392)	0	(5,486,392)
Nonmandatory Transfers			
Transfers	0	0	0
	<hr/>		
Total Transfers	0	0	0
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Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			
NET INCREASE(DECREASE) FOR THE YEAR	(5,486,392)	0	(5,486,392)
Fund Balances at Beginning of Year (7/1/27)	189,819	0	189,819
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FUND BALANCES AT END OF YEAR	(5,296,573)	0	(5,296,573)
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