



October 1, 2023

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

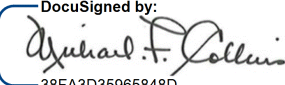
Honorable Michael D. Hurley
Clerk of the Senate
Room 335
State House
Boston, MA 02133

Dear Clerk James and Clerk Hurley:

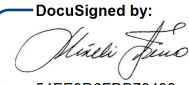
As required by Mass. General Laws, Chapter 75, Section 43(f), we are pleased to “submit to the Clerks of the Senate and the House of Representatives, a report of the activities of MassBiologics within ninety days after the end of the fiscal year.” This is the twenty-sixth year of submitting such an annual report as required by the legislation (Chapter 334 of the Acts of 1996), which transferred the biologic laboratories of the State Laboratory Institute (now called MassBiologics of UMass Chan Medical School) from the Commonwealth’s Department of Public Health to the University of Massachusetts.

If you have any questions, please contact Mireli Fino, Executive Vice Chancellor for MassBiologics, 460 Walk Hill St., Boston, MA 02126, via phone at (617) 474-3251.

Respectfully,

DocuSigned by:

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Michael F. Collins, M.D., FACP
Senior Vice President for the Health Sciences, UMass
Chancellor, UMass Chan Medical School

DocuSigned by:

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Mireli Fino, MBA
Executive Vice Chancellor
MassBiologics of UMass Chan Medical School



**A REPORT OF THE ACTIVITIES OF MASSBIOLOGICS
FISCAL YEAR 2023**

AS REQUIRED BY CHAPTER 75, SECTION 43(F)

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

October 1, 2023

**BY
MASSBIOLOGICS of the
UNIVERSITY OF MASSACHUSETTS CHAN MEDICAL SCHOOL**



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1. INTRODUCTION

This annual report is submitted, as required under Mass. General Laws, Chapter 75, Section 43(f), on the activities of MassBiologics of the University of Massachusetts Chan Medical School. This is the twenty-sixth year of such annual reporting.

The following sections provide the required information as follows:

Part 2, Prior Fiscal Year (FY23) Information, pursuant to the 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) FY23 Statement of Revenues and Expenditures and Other Changes; and (2) FY23 Balance Sheet. Included herein is information related to appropriated funds for the prior fiscal year, also as required by the legislation.

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



2. PRIOR FISCAL YEAR (FY23) INFORMATION

This section of the report presents the specific information required under the legislation for the prior fiscal year (FY23: July 1, 2022 - June 30, 2023). This is the twenty-sixth full year in which MassBiologics has operated within and through the University of Massachusetts. The effective date of the transfer of the biologic laboratories of the State Laboratory Institute (MassBiologics) from the Commonwealth's Department of Public Health to the University of Massachusetts was January 1, 1997.

a. Patents and Licensing:

MassBiologics had no patents issued in FY23.

b. Collaboration and CDMO Service Agreements Entered Into:

MassBiologics previously entered into a series of research and collaboration agreements as follows:

- 1) Oregon Health and Science University for research into a proprietary COVID-19 antibody, effective July 23, 2020.
- 2) Vaccine Research Center for collaboration related to the NIH Non-Human Primate Reagent Resource, effective December 30, 2020.
- 3) University of Florida for research into SARS-COV2, effective October 13, 2020.
- 4) Duke University for research into a proprietary monoclonal antibody (mAb), effective February 26, 2021.
- 5) Wake Forest University for research into pneumoniae mAbs, effective January 4, 2021.
- 6) New York Structural Biology Center for research into SARS-COV2, effective March 12, 2021.
- 7) Fred Hutchinson Cancer Research Center for research into CD33 therapeutics, effective June 2, 2021.
- 8) Naval Medical Research Unit-6 for research into pre-exposure prophylaxis against all major pathogenic Enterotoxigenic Escherichia coli (ETEC) strains effective March 11, 2022.

The contracts listed above remain active, but the Research and Administration related to these contracts has been transferred to the main UMass Chan Medical School campus in Worcester, Massachusetts, and will not be listed in next year's FY24 MassBiologics Annual Report.



MassBiologics Contract Development and Manufacturing Services in FY23 include:

- 1) Two new clients signing Master Service Agreements.
- 2) Four existing clients continuing their programs.
- 3) Thirty-nine new project-specific service agreements were executed in FY23.
- 4) One client program received conditional commercial approval in Europe for a gene therapy product manufactured at MassBiologics. Total CDMO revenue recognized in FY23 was \$21M.

c. Grants and Contracts Awarded:

Gates Foundation - Award of \$7,961,586 was received from the Bill and Melinda Gates Foundation effective May 4, 2017 through December 31, 2021 with a no cost extension through February 1, 2024.

MTEC - Award of \$4,522,024 was received from Advanced Technology International effective October 1, 2021 through March 31, 2023.

R01 Grant - Award of \$3,382,574 was received from NIH-Institute of Allergy & Infectious Disease effective August 1, 2021 through July 31, 2026.

U24 Grant - Award of \$7,994,044 was received from NIH-Institute of Allergy & Infectious Disease effective June 14, 2021 through March 31, 2026.

R24 Grant - Award of \$2,261,280 was received from the NIH effective August 1, 2020 through July 31, 2024.

P40 Grant - Award of \$3,140,024 was received from the NIH effective January 1, 2020 through December 31, 2024. In addition, a supplemental award of \$323,571 was received.

DOD - Award of \$1,539,634 was received from the Department of Defense effective September 1, 2021 through August 31, 2023.

NIIMBL - Award of \$69,954 was received from the University of Delaware effective September 1, 2021 through February 28, 2023.

NIIMBL - Award of \$351,580 was received from the University of Delaware effective November 1, 2021 through July 31, 2022.

NIIMBL - Award of \$284,887 was received from the University of Delaware effective November 1, 2021 through October 31, 2022.



OHSU Grant - Award of \$311,880 was received from Oregon Health and Science University effective July 23, 2020 through June 30, 2025.

HRI – Award of \$1,238,184 was received from Health Research Inc. effective September 16, 2019 through September 15, 2024.

Please note that at the start of the current FY24, twelve (12) of the above listed grant awards have moved from the operations of MassBiologics in Mattapan to the main UMass Chan Medical School campus in Worcester. Principal Investigators conducting the related research are now doing so at the main Medical School campus. Accordingly, these grants will not be listed in next year's FY24 MassBiologics Annual Report.

d. Status of Existing Agreements, Royalties, and Other Benefits:

MassBiologics had the following major existing agreements in FY23.

Medimmune (formerly Molecular Vaccines), license for Synagis, a therapeutic for Respiratory Syncytial Virus 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.

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 the 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.

The Materials Cooperative Research and Development Agreement (M-CRADA) was entered into 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 on April 20, 2009 for antibodies against *C. difficile*. This agreement remains in place to support the 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 the distribution of Tetanus and Diphtheria Vaccine (Td) in USA, Canada, and Europe under the TDVAX tradename. This agreement remains in effect.

e. Revenues, Expenditures, Assets, and Liabilities:

On the pages that follow, please find two schedules: (1) FY23 Statement of Revenues and Expenditures and Other Charges; and (2) FY23 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 DPH appropriated funding (\$739,615) in support of Tetanus and Diphtheria Vaccine (Td) production and manufacturing at MassBiologics. These funds only partially support the necessary staff, supplies, and equipment used in the production of the Td vaccine that is distributed to residents of Massachusetts without charge. During FY24, MassBiologics will begin a review of its Td program resulting from an ongoing external analysis of the involved reagent used in the manufacturing process, and the prevalence in the marketplace of the competing Tdap vaccine.
- License and Royalty Fees represent 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 and 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 FY23. In calendar year 2008, MassBiologics received its licensure from the FDA to bring its new production facility online. MassBiologics continues to manufacture clinical material in the new facility to support its IND activities.



The production facility (Mattapan I) is located at the old Boston State Hospital location in Mattapan, Massachusetts. This location and permitted “use” were authorized by the legislature in July 2000 and the facility opened in October 2005. To support the costs of this facility, the Worcester City Campus Corporation (WCCC) borrowed in FY02 in reliance on its lease with the University of Massachusetts Chan Medical School acting on behalf of MassBiologics. WCCC’s sole corporate member is the University of Massachusetts and its corporate purpose is to foster, support and promote the University of Massachusetts in all of its locations. The “Plant Fund” represents payment of the lease payments supporting the bonds, as well as other capital costs associated with WCCC, the University of Massachusetts Chan Medical School, and the capital needs and operations of MassBiologics.

The 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 constructing Mattapan II, WCCC borrowed \$35M in FY07 in reliance on its lease with the University of Massachusetts Chan Medical School acting on behalf of MassBiologics.

Thereafter, it was determined that MassBiologics would benefit from consolidating its operations in Jamaica Plain (within the Hinton State Laboratory building) to one campus in Mattapan by making facility modifications to the Mattapan Campus. These modifications were completed by June 2013, making it possible for MassBiologics to leave its Jamaica Plain campus effective June 30, 2013, ending the biologic laboratories of the State Laboratory Institute’s 119-year tenancy at that Jamaica Plain campus.

Commissioning and validation activities were completed at the Mattapan facility and the FDA inspected and approved the manufacturing of Tetanus Diphtheria Vaccine (Td).

In FY15, it was determined that the Massachusetts Accelerator for Biomanufacturing (MAB) facility in Fall River, Massachusetts, developed under guidance from 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 MassBiologics of UMass Chan. Grants totaling \$10M from the MLSC and MassWorks were invested in the facility located at 1240 Innovation Way in Fall River 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.

MassBiologics 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 above were refinanced, thereby reducing the future debt service payments.



During FY24, as it continues its strategic evaluation of its assets, facilities, opportunities, challenges, and overall financial outlook, MassBiologics will consider, where necessary or practicable, certain operational efficiencies.



University of Massachusetts Biologic Laboratories
Statement of Revenues, Expenditures and Other Changes
For the Period July 1, 2022 Through June 30, 2023
(Unaudited)

	CURRENT FUND	APPROPRIATED FUNDS	TOTAL
REVENUE AND OTHER ADDITIONS:			
Product Sales	27,789,692	0	27,789,692
Restricted Grants & Contracts	29,894	0	29,894
State Appropriations/DPH	0	739,615	739,615
Royalty Fees and Interest	21,763,449	0	21,763,449
Recovery of Indirect Costs	628,113	0	628,113
Other Income	482,375	0	482,375
Total Revenue and Other Additions	50,693,524	739,615	51,433,140
EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	16,828,788	403,085	17,231,873
Fringe Benefits	5,066,752	123,272	5,190,024
Supplies and Services	35,999,889	213,258	36,213,147
Depreciation	1,764,931	0	1,764,931
Total Expenditures and Other Deductions	59,660,360	739,615	60,399,975
Net Increase/(Decrease) Before Transfers	(8,966,836)	0	(8,966,836)
Nonmandatory Transfers			
Transfers	(2,207,265)	0	(2,207,265)
Total Transfers	(2,207,265)	0	(2,207,265)
Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			
NET INCREASE(DECREASE) FOR THE YEAR	(11,174,101)	0	(11,174,100)
Fund Balances at Beginning of Year (7/1/22)	29,796,828	0	29,796,828
FUND BALANCES AT END OF YEAR	18,622,727	0	18,622,727



University of Massachusetts Biologic Laboratories
Balance Sheet
As of June 30, 2023
(Unaudited)

	CURRENT FUND FY23	PLANT FUND FY23	TOTAL FY23
Assets			
Cash	7,752,493	184,312	7,936,805
Accounts Receivable	7,417,574	0	7,417,574
Inventory	4,819,479	0	4,819,479
Prepaid Expenses	5,333,885	0	5,333,885
Buildings & Equipment	0	12,403,007	12,403,007
Other Assets	0	0	0
Total Assets	25,323,430	12,587,319	37,910,749
Liabilities			
Accounts Payable	2,404,235	0	2,404,235
Employee-Related Accruals	482,635	0	482,635
Other Liabilities	16,401,152	0	16,401,152
Total Liabilities	19,288,022	0	19,288,022
Fund Balances	6,035,409	12,587,319	18,622,727
Total Liabilities and Fund Balance	25,323,430	12,587,319	37,910,749

Financial Plans



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	25,724,000	0	25,724,000
State Appropriations/DPH	0	600,000	600,000
Royalty Fees and Interest	15,000,000	0	15,000,000
Other Income	500,000	0	500,000
Total Revenue and Other Additions	41,224,000	600,000	41,824,000
EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	13,500,000	0	13,500,000
Fringe Benefits	4,100,000	0	4,100,000
Supplies and Services	21,924,000	600,000	22,524,000
Depreciation	1,700,000	0	1,700,000
Total Expenditures and Other Deductions	41,224,000	600,000	41,824,000
Net Increase/(Decrease) Before Transfers	0	0	0
Nonmandatory Transfers			
Transfers	0	0	0
Total Transfers	0	0	0
Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			
NET INCREASE(DECREASE) FOR THE YEAR	0	0	0
Fund Balances at Beginning of Year (7/1/23)	18,622,727	0	18,622,727
FUND BALANCES AT END OF YEAR	18,622,727	0	18,622,727



UMass Chan MEDICAL SCHOOL

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

	CURRENT FUND	APPROPRIATED FUNDS	TOTAL
REVENUE AND OTHER ADDITIONS:			
Product Sales	25,836,000	0	25,836,000
State Appropriations/DPH	0	600,000	600,000
Royalty Fees and Interest	15,000,000	0	15,000,000
Other Income	400,000	0	400,000
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Total Revenue and Other Additions	41,236,000	600,000	41,836,000
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EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	11,220,000	0	11,220,000
Fringe Benefits	3,468,000	0	3,468,000
Supplies and Services	24,848,000	600,000	25,448,000
Depreciation	1,700,000	0	1,700,000
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Total Expenditures and Other Deductions	41,236,000	600,000	41,836,000
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Net Increase/(Decrease) Before Transfers	0	0	0
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Nonmandatory Transfers			
Transfers	0	0	0
	<hr/>		
Total Transfers	0	0	0
<hr/>			
Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			
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NET INCREASE(DECREASE) FOR THE YEAR	0	0	0
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Fund Balances at Beginning of Year (7/1/24)	18,622,727	0	18,622,727
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FUND BALANCES AT END OF YEAR	18,622,727	0	18,622,727
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University of Massachusetts Biologic Laboratories
Statement of Revenues, Expenditures and Other Changes
For the Period July 1, 2025 Through June 30, 2026
(Unaudited)

	<u>CURRENT FUND</u>	<u>APPROPRIATED FUNDS</u>	<u>TOTAL</u>
REVENUE AND OTHER ADDITIONS:			
Product Sales	26,000,000	0	26,000,000
State Appropriations/DPH	0	0	0
Royalty Fees and Interest	15,000,000	0	15,000,000
Other Income	400,000	0	400,000
Total Revenue and Other Additions	41,400,000	0	41,400,000
EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	11,444,400	0	11,444,400
Fringe Benefits	3,537,360	0	3,537,360
Supplies and Services	24,718,240	0	24,718,240
Depreciation	1,700,000	0	1,700,000
Total Expenditures and Other Deductions	41,400,000	0	41,400,000
Net Increase/(Decrease) Before Transfers	0	0	0
Nonmandatory Transfers			
Transfers	0	0	0
Total Transfers	0	0	0
Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			
NET INCREASE(DECREASE) FOR THE YEAR	0	0	0
Fund Balances at Beginning of Year (7/1/25)	18,622,727	0	18,622,727
FUND BALANCES AT END OF YEAR	18,622,727	0	18,622,727