



MassBiologics
Medicine for Better

October 1, 2022

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

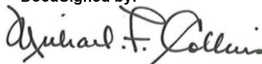
Honorable Michael D. Hurley
Clerk of the Senate
Room 335
State House
Boston, MA 02133

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 Mass Biologics within ninety days after the end of the fiscal year.” This is the twenty-fifth year of such annual report required by the legislation, which transferred MassBiologics from the Department of Public Health to the University of Massachusetts.

If you have any questions, please contact Mireli Fino, MassBiologics, 460 Walk Hill St., Boston, MA 02126, (617) 474-3251.

Sincerely,

DocuSigned by:

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

DocuSigned by:

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

**A REPORT OF THE ACTIVITIES OF MASSBIOLOGICS
FISCAL YEAR 2022**

AS REQUIRED BY CHAPTER 75, SECTION 43(F)

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

&

CLERK OF THE SENATE

October 1, 2022

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-fifth year of such annual report.

The following sections provide the required information as follows:

Part 2, Prior Fiscal Year (FY22) 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) FY22 Statement of Revenues and Expenditures and Other Changes and (2) FY22 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 (FY22) INFORMATION

This section of the report presents the specific information indicated in the legislation related to the prior fiscal year (FY22: July 1, 2021 - June 30, 2022). This is the twenty-fifth 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 with claims allowed in FY22:

- 1) Human Antibodies Against Rabies and Uses Thereof
5/31/2022 China Patent No: ZL201680059761.1
- 2) Anti-OPSA Antibodies and Methods of Use
5/18/2021 Europe Patent No: 3180024

b. Collaboration and CDMO Service Agreements entered into

MassBiologics 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) Columbia University for research into SARS COV2, effective August 24, 2020.
- 3) Vaccine Research Center for collaboration related to the NIH Non-Human Primate Reagent Resource, effective December 30, 2020.
- 4) University of Florida for research into a SARS-COV2, effective October 13, 2020.
- 5) Duke University for research into a proprietary mAb, effective February 26, 2021.
- 6) Wake Forrest University for research into pneumoniae mAbs, effective January 4, 2021.
- 7) New York Structural Biology Center for research into SARS COV2, effective March 12, 2021.
- 8) Fred Hutchinson Cancer Research Center for research into CD33 therapeutics, effective June 2, 2021.
- 9) Naval Medical Research Unit-6 for research into pre-exposure prophylaxis against all major pathogenic Enterotoxigenic Escherichia coli (ETEC) strains effective March 11, 2022.

MassBiologics Contract Development and Manufacturing Services in FY22 include:

- 1) Two new clients signing Master Service Agreements.
- 2) Four clients extending the terms of previously executed Master Service Agreements.

- 3) Eighty-three project specific service agreements were executed in FY22 generating \$22.1M in sales. One client program filed for commercial approval in Europe for a gene therapy product manufactured at MassBiologics. Total CDMO revenue recognized in FY22 was \$22M.

c. Grants and Contracts Awarded

Gates Foundation - Award of \$7,961,586 was received from Bill and Melinda Gates Foundation effective May 4, 2017 through December 31, 2021 with a no cost extension through December 31, 2021. No funding was received in FY22.

MTEC - Award of \$4,522,024 was received from Advanced Technology International effective October 1, 2021 through March 31, 2023. \$1,598,235 of funding was received in FY22.

R01 Grant - Award of \$3,382,574 was received from NIH-Nat'l Inst. of Allergy & Infectious Disease effective August 1, 2021 through July 31, 2026. \$266,080 of funding was received in FY22.

U24 Grant - Award of \$7,994,044 was received from NIH-Nat'l Inst. of Allergy & Infectious Disease effective June 14, 2021 through March 31, 2026. \$1,817,398 of funding was received in FY22.

R24 Grant - Award of \$2,261,280 was received from National Institutes of Health effective August 1, 2020 through July 31, 2024. \$361,865 of funding was received in FY22.

P40 Grant - Award of \$3,140,024 was received from National Institutes of Health effective January 1, 2020 through December 31, 2024. \$429,384 of funding was received in FY22. In addition, a supplemental award of \$323,571 was received of which \$123,344 of funding was received in FY22.

DOD - Award of \$273,371 was received from Department of Defense effective November 1, 2018 with a no cost extension through October 31, 2021. \$97,656 of funding was received in FY22.

DOD - Award of \$1,539,634 was received from Department of Defense effective September 1, 2021 through August 31, 2023. \$427,041 of funding was received in FY22.

DOD - Award of \$869,052 was received from Department of Defense effective July 15, 2018 through July 14, 2021. \$7,754 of funding was received in FY22.

NIIMBL - Award of \$375,000 was received from University of Delaware effective August 17, 2020 through August 16, 2021. \$51,333 of funding was received in FY22.

NIIMBL - Award of \$411,064 was received from University of Delaware effective September 1, 2019 with a no cost extension through November 30, 2021. \$172,410 of funding was received in FY22.

NIIMBL - Award of \$75,000 was received from University of Delaware effective October 1, 2020 with a no cost extension through October 31, 2021. \$46,631 of funding was received in FY22. An additional award of \$25,000 was received effective November 1, 2021 through April 30, 2022. \$19,841 of funding was received in FY22.

NIIMBL - Award of \$69,954 was received from University of Delaware effective September 1, 2021 through February 28, 2023. \$26,463 of funding was received in FY22.

NIIMBL - Award of \$351,580 was received from University of Delaware effective November 1, 2021 through July 31, 2022. \$348,119 of funding was received in FY22.

NIIMBL - Award of \$284,887 was received from University of Delaware effective November 1, 2021 through October 31, 2022. \$118,574 of funding was received in FY22.

OHSU Grant - Award of \$311,880 was received from Oregon Health and Science University effective July 23, 2020 through June 30, 2025. \$58,883 of funding was received in FY22.

HRI – Amended Award of \$1,238,184 was received from Health Research Inc. effective September 16, 2019 through September 15, 2024. \$179,576 of funding was received in FY22.

d. Status of existing agreements, royalties and other benefits

MassBiologics had the following major existing agreements in FY22.

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 purchased 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.

The 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.

e. Revenues, expenditures, assets and liabilities

On the pages that follow, please find two schedules: (1) FY22 Statement of Revenues and Expenditures and Other Charges and (2) FY22 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 \$728,473. These funds only partially support staff and provide the supplies and equipment used in the production of vaccine which is distributed to residents of Massachusetts without charge. The vaccine that is provided is Tetanus Diphtheria Vaccine (Td).
- 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 FY22. 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 the 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 it was determined that the MAB facility 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 MassBiologics. Grants totaling \$10M from the MLSC and MassWorks were invested in the facility located at 1240 Innovation Way 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, 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, 2021 Through June 30, 2022
(Unaudited)

	CURRENT FUND	APPROPRIATED FUNDS	TOTAL
REVENUE AND OTHER ADDITIONS:			
Product Sales	34,235,998	0	34,235,998
Restricted Grants & Contracts	6,285,355	0	6,285,355
State Appropriations/DPH	0	728,473	728,473
Royalty Fees and Interest	18,736,259	0	18,736,259
Recovery of Indirect Costs	827,334	0	827,334
Other Income	426,903	0	426,903
Total Revenue and Other Additions	60,511,849	728,473	61,240,322
EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	18,586,512	403,085	18,989,597
Fringe Benefits	5,498,073	123,413	5,621,486
Supplies and Services	43,709,207	201,975	43,911,182
Depreciation	2,038,936	0	2,038,936
Total Expenditures and Other Deductions	69,832,728	728,473	70,561,201
Net Increase/(Decrease) Before Transfers	(9,320,879)	0	(9,320,879)
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	(9,320,879)	0	(9,320,879)
Fund Balances at Beginning of Year (7/1/21)	39,117,707	0	39,117,707
FUND BALANCES AT END OF YEAR	29,796,828	0	29,796,828

University of Massachusetts Biologic Laboratories
Balance Sheet
As of June 30, 2022
(Unaudited)

	CURRENT FUND	PLANT FUND	TOTAL
	FY22	FY22	FY22
Assets			
Cash	17,925,447	1,078,262	19,003,710
Accounts Receivable	8,944,056	0	8,944,056
Inventory	7,307,455	0	7,307,455
Prepaid Expenses	4,478,342	0	4,478,342
Buildings & Equipment	0	12,867,465	12,867,465
Other Assets	0	0	0
Total Assets	38,655,300	13,945,727	52,601,027
Liabilities			
Accounts Payable	2,861,886	0	2,861,886
Employee-Related Accruals	977,630	0	977,630
Other Liabilities	18,964,684	0	18,964,684
Total Liabilities	22,804,199	0	22,804,199
Fund Balances	15,851,101	13,945,727	29,796,828
Total Liabilities and Fund Balance	38,655,300	13,945,727	52,601,027

Financial Plans

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	54,132,000	0	54,132,000
Restricted Grants & Contracts	6,040,000	0	6,040,000
State Appropriations/DPH	0	672,000	672,000
Royalty Fees and Interest	13,604,000	0	13,604,000
Recovery of Indirect Costs	649,000	0	649,000
Other Income	1,230,000	0	1,230,000
Total Revenue and Other Additions	75,655,000	672,000	76,327,000
EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	25,171,500	0	25,171,500
Fringe Benefits	8,092,500	0	8,092,500
Supplies and Services	42,391,000	672,000	43,063,000
Depreciation	0	0	0
Total Expenditures and Other Deductions	75,655,000	672,000	76,327,000
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 (7/1/21)	29,796,828	0	29,796,828
FUND BALANCES AT END OF YEAR	29,796,828	0	29,796,828

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

	CURRENT FUND	APPROPRIATED FUNDS	TOTAL
REVENUE AND OTHER ADDITIONS:			
Product Sales	55,475,000	0	55,475,000
Restricted Grants & Contracts	6,384,000	0	6,384,000
State Appropriations/DPH	0	672,000	672,000
Royalty Fees and Interest	13,944,000	0	13,944,000
Recovery of Indirect Costs	690,000	0	690,000
Other Income	1,260,000	0	1,260,000
Total Revenue and Other Additions	77,753,000	672,000	78,425,000
EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	25,854,000	0	25,854,000
Fringe Benefits	8,311,500	0	8,311,500
Supplies and Services	43,587,500	672,000	44,259,500
Depreciation	0	0	0
Total Expenditures and Other Deductions	77,753,000	672,000	78,425,000
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 (7/1/22)	29,796,828	0	29,796,828
FUND BALANCES AT END OF YEAR	29,796,828	0	29,796,828

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	56,847,000	0	56,847,000
Restricted Grants & Contracts	6,754,000	0	6,754,000
State Appropriations/DPH	0	672,000	672,000
Royalty Fees and Interest	14,293,000	0	14,293,000
Recovery of Indirect Costs	735,000	0	735,000
Other Income	1,292,000	0	1,292,000
Total Revenue and Other Additions	79,921,000	672,000	80,593,000
EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	26,559,000	0	26,559,000
Fringe Benefits	8,537,000	0	8,537,000
Supplies and Services	44,825,000	672,000	45,497,000
Depreciation	0	0	0
Total Expenditures and Other Deductions	79,921,000	672,000	80,593,000
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)	29,796,828	0	29,796,828
FUND BALANCES AT END OF YEAR			
	29,796,828	0	29,796,828