

October 31, 2021

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

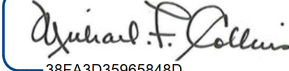
Dear Mr. James and Mr. Hurley:

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-fourth 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 Frank Fazio, MassBiologics, 460 Walk Hill St., Boston, MA 02126, (617) 474-3254.

Sincerely,

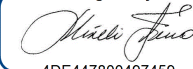
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Michael F. Collins, M.D.  
Chancellor  
University of Massachusetts Chan Medical School

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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 2021**

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

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

**&**

**CLERK OF THE SENATE**

**October 1, 2021**

**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-fourth year of such annual report.

The following sections provide the required information as follows:

Part 2, Prior Fiscal Year (FY21) 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) FY21 Statement of Revenues and Expenditures and Other Changes and (2) FY21 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 (FY21) INFORMATION**

This section of the report presents the specific information indicated in the legislation related to the prior fiscal year (FY21: July 1, 2020 - June 30, 2021). This is the twenty-fourth 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 no patents with claims allowed in FY21.

### **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.

MassBiologics Contract Development and Manufacturing Services was to a degree impacted by a slowdown of client clinical programs due to COVID-19. Business Development achievements include:

- 1) Eight new clients signing Master Service Agreements.
- 2) Eighty-two new service agreements were executed in FY21 generating \$21.9M in sales. Total CDMO revenue recognized in FY21 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. \$964,709 of funding was received in FY21.

U24 Grant - Award of \$9,099,435 was received from NIH-Nat'l Inst. of Allergy & Infectious Disease effective September 29, 2016 through May 31, 2021. \$1,489,619 of funding was received in FY21. An additional, \$353,732 was received for COVID funding of which \$252,970 was received in FY21.

R24 Grant - Award of \$2,702,612 was received from National Institutes of Health effective January 1, 2016 through November 30, 2020. \$135,371 of funding was received in FY21. A new award was received effective August 1, 2020 through July 31, 2024. \$414,113 of funding was received in FY21.

P40 Grant - Award of \$3,140,024 was received from National Institutes of Health effective January 1, 2020 through December 31, 2024. \$473,032 of funding was received in FY21. In addition, a supplemental award of \$323,571 was received of which \$69,160 of funding was received in FY21.

DOD - Award of \$273,371 was received from Department of Defense effective November 1, 2018 with a no cost extension through October 31, 2021. \$37,488 of funding was received in FY21.

DOD - Award of \$869,052 was received from Department of Defense effective July 15, 2018 through July 14, 2021. \$169,298 of funding was received in FY21.

NIIMBL - Award of \$411,064 was received from University of Delaware effective September 1, 2019 through June 30, 2021. \$188,067 of funding was received in FY21.

NIIMBL - Award of \$44,662 was received from University of Delaware effective January 1, 2020 through December 30, 2020. \$ 44,662 of funding was received in FY21.

NIIMBL - Award of \$75,000 was received from University of Delaware effective October 1, 2020 through September 30, 2021. \$1,497 of funding was received in FY21.

NIIMBL - Award of \$375,000 was received from University of Delaware effective August 17, 2020 through August 16, 2021. \$240,674 of funding was received in FY21.

OHSU Grant - Award of \$311,880 was received from Oregon Health and Science University effective July 23, 2020 through June 30, 2025. \$33,718 of funding was received in FY21.

HRI - Award of \$1,248,841 was received from Health Research Inc. effective September 16, 2019 through September 15, 2024. \$209,181 of funding was received in FY21.

WAF Grant – Award of \$1,799,551 was received from The Warren Alpert Foundation effective December 1, 2019 through November 30, 2021. \$1,799,551 of funding was received in FY21.

**d. Status of existing agreements, royalties and other benefits**

MassBiologics had the following major existing agreements in FY21.

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) FY21 Statement of Revenues and Expenditures and Other Charges and (2) FY21 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 \$776,917. 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 FY21. 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, 2020 Through June 30, 2021**  
**(Unaudited)**

	<u>CURRENT</u> <u>FUND</u>	<u>APPROPRIATED</u> <u>FUNDS</u>	<u>TOTAL</u>
<b>REVENUE AND OTHER ADDITIONS:</b>			
Product Sales	32,461,815	0	32,461,815
Restricted Grants & Contracts	6,475,586	0	6,475,586
State Appropriations/DPH	0	776,917	776,917
Royalty Fees and Interest	6,155,822	0	6,155,822
Recovery of Indirect Costs	716,117	0	716,117
Other Income	50,000	0	50,000
	<hr/>		
<b>Total Revenue and Other Additions</b>	<b>45,859,340</b>	<b>776,917</b>	<b>46,636,257</b>
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<b>EXPENDITURES AND OTHER DEDUCTIONS:</b>			
Salaries	19,063,773	403,085	19,466,858
Fringe Benefits	5,977,985	117,799	6,095,783
Supplies and Services	35,018,261	256,033	35,274,294
Depreciation	1,838,113	0	1,838,113
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<b>Total Expenditures and Other Deductions</b>	<b>61,898,132</b>	<b>776,917</b>	<b>62,675,049</b>
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<b>Net Increase/(Decrease) Before Transfers</b>	<b>(16,038,792)</b>	<b>0</b>	<b>(16,038,792)</b>
<b>Nonmandatory Transfers</b>			
Transfers	0	0	0
	<hr/>		
<b>Total Transfers</b>	<b>0</b>	<b>0</b>	<b>0</b>
<hr/>			
<b>Other Changes</b>			
<b>Excess of Restricted Receipts over Transfers to Revenue</b>			
<b>NET INCREASE(DECREASE) FOR THE YEAR</b>	<b>(16,038,792)</b>	<b>0</b>	<b>(16,038,792)</b>
<b>Fund Balances at Beginning of Year (7/1/20)</b>	<b>55,156,499</b>	<b>0</b>	<b>55,156,499</b>
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<b>FUND BALANCES AT END OF YEAR</b>	<b>39,117,707</b>	<b>0</b>	<b>39,117,707</b>
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**University of Massachusetts Biologic Laboratories**  
**Balance Sheet**  
**As of June 30, 2021**  
**(Unaudited)**

	<b>CURRENT FUND FY21</b>	<b>PLANT FUND FY21</b>	<b>TOTAL FY21</b>
<b>Assets</b>			
Cash	24,823,774	1,326,155	26,149,929
Accounts Receivable	1,443,151	23,348	1,466,499
Inventory	13,238,049		13,238,049
Prepaid Expenses	3,566,599		3,566,599
Buildings & Equipment	0	14,462,875	14,462,875
Other Assets	0	0	0
<b>Total Assets</b>	<b>43,071,573</b>	<b>15,812,378</b>	<b>58,883,951</b>
<b>Liabilities</b>			
Accounts Payable	2,403,310	242,926	2,646,235
Employee-Related Accruals	565,203	0	565,203
Other Liabilities	16,554,805	0	16,554,805
<b>Total Liabilities</b>	<b>19,523,318</b>	<b>242,926</b>	<b>19,766,243</b>
<b>Fund Balances</b>	<b>23,548,255</b>	<b>15,569,452</b>	<b>39,117,707</b>
<b>Total Liabilities and Fund Balance</b>	<b>43,071,573</b>	<b>15,812,378</b>	<b>58,883,951</b>

# Financial Plans

**University of Massachusetts Biologic Laboratories**  
**Statement of Revenues, Expenditures and Other Changes**  
**For the Period July 1, 2021 Through June 30, 2022**  
**(Unaudited)**

	<b>CURRENT FUND</b>	<b>APPROPRIATED FUNDS</b>	<b>TOTAL</b>
<b>REVENUE AND OTHER ADDITIONS:</b>			
Product Sales	56,091,000	0	56,091,000
Restricted Grants & Contracts	6,175,000	0	6,175,000
State Appropriations/DPH	0	672,000	672,000
Royalty Fees and Interest	13,272,000	0	13,272,000
Recovery of Indirect Costs	672,000	0	672,000
Other Income	1,200,000	0	1,200,000
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<b>Total Revenue and Other Additions</b>	<b>77,410,000</b>	<b>672,000</b>	<b>78,082,000</b>
<b>EXPENDITURES AND OTHER DEDUCTIONS:</b>			
Salaries	24,637,000	0	24,637,000
Fringe Benefits	8,122,000	0	8,122,000
Supplies and Services	41,900,000	672,000	42,572,000
Depreciation	0	0	0
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<b>Total Expenditures and Other Deductions</b>	<b>74,659,000</b>	<b>672,000</b>	<b>75,331,000</b>
<b>Net Increase/(Decrease) Before Transfers</b>	<b>2,751,000</b>	<b>0</b>	<b>2,751,000</b>
<b>Nonmandatory Transfers</b>			
Transfers	0	0	0
	<hr/>		
<b>Total Transfers</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Other Changes</b>			
Excess of Restricted Receipts over Transfers to Revenue			
<b>NET INCREASE(DECREASE) FOR THE YEAR</b>	<b>2,751,000</b>	<b>0</b>	<b>2,751,000</b>
<b>Fund Balances at Beginning of Year (7/1/21)</b>	<b>39,117,707</b>	<b>0</b>	<b>39,117,707</b>
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<b>FUND BALANCES AT END OF YEAR</b>	<b>41,868,707</b>	<b>0</b>	<b>41,868,707</b>

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

	<u>CURRENT FUND</u>	<u>APPROPRIATED FUNDS</u>	<u>TOTAL</u>
<b>REVENUE AND OTHER ADDITIONS:</b>			
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
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<b>Total Revenue and Other Additions</b>	<b>75,655,000</b>	<b>672,000</b>	<b>76,327,000</b>
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<b>EXPENDITURES AND OTHER DEDUCTIONS:</b>			
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
	<hr/>		
<b>Total Expenditures and Other Deductions</b>	<b>75,655,000</b>	<b>672,000</b>	<b>76,327,000</b>
<hr/>			
<b>Net Increase/(Decrease) Before Transfers</b>	<b>0</b>	<b>0</b>	<b>0</b>
<hr/>			
<b>Nonmandatory Transfers</b>			
Transfers	0	0	0
	<hr/>		
<b>Total Transfers</b>	<b>0</b>	<b>0</b>	<b>0</b>
<hr/>			
<b>Other Changes</b>			
Excess of Restricted Receipts over Transfers to Revenue			
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<b>NET INCREASE(DECREASE) FOR THE YEAR</b>	<b>0</b>	<b>0</b>	<b>0</b>
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<b>Fund Balances at Beginning of Year (7/1/22)</b>	<b>41,868,707</b>	<b>0</b>	<b>41,868,707</b>
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<b>FUND BALANCES AT END OF YEAR</b>	<b>41,868,707</b>	<b>0</b>	<b>41,868,707</b>

**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>
<b>REVENUE AND OTHER ADDITIONS:</b>			
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
	<hr/>		
<b>Total Revenue and Other Additions</b>	<b>77,753,000</b>	<b>672,000</b>	<b>78,425,000</b>
<hr/>			
<b>EXPENDITURES AND OTHER DEDUCTIONS:</b>			
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
	<hr/>		
<b>Total Expenditures and Other Deductions</b>	<b>77,753,000</b>	<b>672,000</b>	<b>78,425,000</b>
<hr/>			
<b>Net Increase/(Decrease) Before Transfers</b>	<b>0</b>	<b>0</b>	<b>0</b>
<hr/>			
<b>Nonmandatory Transfers</b>			
Transfers	0	0	0
	<hr/>		
<b>Total Transfers</b>	<b>0</b>	<b>0</b>	<b>0</b>
<hr/>			
<b>Other Changes</b>			
Excess of Restricted Receipts over Transfers to Revenue			
<hr/>			
<b>NET INCREASE(DECREASE) FOR THE YEAR</b>	<b>0</b>	<b>0</b>	<b>0</b>
<hr/>			
<b>Fund Balances at Beginning of Year (7/1/23)</b>	<b>41,868,707</b>	<b>0</b>	<b>41,868,707</b>
<hr/>			
<b>FUND BALANCES AT END OF YEAR</b>	<b>41,868,707</b>	<b>0</b>	<b>41,868,707</b>