



MassBiologics

Medicine for Better Lives



October 1, 2019

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

Honorable William F. Welch
Clerk of the Senate
Room 335
State House
Boston, MA 02133

Dear Mr. James and Mr. Welch:

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-third 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,

A handwritten signature in blue ink, reading 'Michael F. Collins'.

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

A handwritten signature in blue ink, reading 'Mark S. Klempner'.

Mark S. Klempner, M.D.
Executive Vice Chancellor, MassBiologics
University of Massachusetts Medical School

**A REPORT OF THE ACTIVITIES OF MASSBIOLOGICS
FISCAL YEAR 2019**

AS REQUIRED BY CHAPTER 75, SECTION 43(F)

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

&

CLERK OF THE SENATE

October 1, 2019

BY

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

TABLE OF CONTENTS

1. INTRODUCTION.....	3
2. PRIOR FISCAL YEAR (FY19) INFORMATION	4
a. Patents and Licensing.....	4
b. Agreements entered into	4
c. Grants and Contracts Awarded.....	5
d. Status of existing agreements, royalties and other benefits	6
e. Revenues, expenditures, assets and liabilities	6
f. FY19 Statement of Revenues, Expenditures and Other Changes	9
g. FY19 Balance Sheet.....	10
3. FINANCIAL PLANS.....	11
a. FY20 Projected Statement of Revenues, Expenditures and Other Changes	12
b. FY21 Projected Statement of Revenues, Expenditures and Other Changes	13
c. FY22 Projected Statement of Revenues, Expenditures and Other Changes	14

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 Medical School. This is the twenty-third year of such annual report.

The following sections provide the required information as follows:

Part 2, Prior Fiscal Year (FY19) 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) FY19 Statement of Revenues and Expenditures and Other Changes and (2) FY19 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 (FY19) INFORMATION

This section of the report presents the specific information indicated in the legislation related to the prior fiscal year (FY19: July 1, 2018 - June 30, 2019). This is the twenty-third 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 has had three patents with claims allowed in FY19:

Rabies HuMAb-1 and Uses Thereof

- 1) 10/09/2018 Brazil Patent No. PI 0606790-5
- 2) 04/09/2019 Canada Patent No. 2596697

C. difficile mAb and Uses Thereof

- 1) 02/26/2019 Canada Patent No. 2553946

b. Agreements entered into

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

- 1) New York Structural Biology Center for research into ETEC therapeutics, effective August 9, 2018.
- 2) Lumen Bioscience, for research into ETEC therapeutics, October 22, 2018.
- 3) A-Alpha Bio Inc. research into Lyme therapeutics effective April 11, 2019.
- 4) University of California San Diego, for research ETEC expression platforms effective September 5, 2018.
- 5) Johns Hopkins University, for research into manufacturing methods effective December 13, 2018.
- 6) Rensselaer Polytechnic Institute, for research into manufacturing methods, effective December 13, 2018.
- 7) Gigagen Inc., for antibody production, effective June 12, 2019.

MassBiologics' Contract Development and Manufacturing Services enjoyed continued growth in FY19. Highlights include three new clients signing Master Service Agreements; one South Coast client signed agreements to execute process validation

campaigns to support Biologics License Application submission and commercialization of a gene therapy product and seventy-four new service agreements were executed generating \$27.9M in sales. (\$7.9M from Mattapan Facility and \$20M from South Coast Facility). Contract Manufacturing Services revenue recognized in FY19 was \$19M.

c. Grants and Contracts Awarded

Gates Foundation – Award of \$3,647,714 was received from Bill and Melinda Gates Foundation effective May 4, 2017 through November 30, 2019. \$1,289,790 of funding was received in FY19.

U24 Grant – Award of \$8,645,123 was received from NIH-National Institute of Allergy & Infectious Disease effective September 29, 2016 through May 31, 2021. \$1,455,286 of funding was received in FY19.

R24 Grant - Award of \$2,081,406 was received from National Institutes of Health effective January 1, 2016 through November 30, 2019. \$555,922 of funding was received in FY19.

UCSF Grant – Award of \$414,680 was received from University of California San Francisco effective July 14, 2016 through June 30, 2021. \$87,598 of funding was received in FY19.

MGH Grant – Award of \$406,345 was received from Massachusetts General Hospital effective December 1, 2016 through October 31, 2018. \$32,373 of funding was received in FY19.

CTR Advancing Translational Sciences – Award of \$11,616 was received from NIH-National Center Advancing Transitional Sciences effective August 14, 2015 through March 31, 2020. \$7,624 of funding was received in FY19.

Voyager – Award of \$125,000 was received from Voyager Therapeutics effective April 1, 2018 through March 31, 2020. \$34,329 of funding was received in FY19.

DOD – Award of \$1,142,423 was received from Department of Defense effective July 15, 2018 through July 14, 2021. \$224,167 of funding was received in FY19.

University of Delaware – Award of \$626,179 was received from University of Delaware effective January 1, 2019 through June 30, 2020. \$132,826 of funding was received in FY19.

MLSC – Award of \$447,556 was received from Massachusetts Life Sciences Center effective April 2, 2019 through June 30, 2020. \$447,556 of funding was received in FY19.

d. Status of existing agreements, royalties and other benefits

MassBiologics had the following major existing agreements in FY19:

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.

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 continued clinical development 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 for Td Vaccine in USA, Canada and Europe was entered on July 1, 2015 and remains in effect through December 31, 2021.

Sale of Reagents which are the by-products of the major manufacturing products of MassBiologics. MassBiologics makes these reagents available for research purposes.

e. Revenues, expenditures, assets and liabilities

On the pages that follow, please find two schedules: (1) FY19 Statement of Revenues and Expenditures and Other Charges and (2) FY19 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 / Department of Public Health (DPH) represents the DPH appropriated fund support of the effort at the Biologic Laboratories of \$790,600. 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. In FY19, the plant fund continued to also be used to conclude the new facility expenses.

The core activities of MassBiologics remained consistent through FY19. In calendar year 2008, the 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 new 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 new facility, Worcester City Campus Corporation borrowed in FY02 in reliance on its lease with the University of Massachusetts 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 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 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 Td vaccine.

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. The previously identified 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 the last four years. The final payment will be in FY21.

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, 2018 Through June 30, 2019
(Unaudited)

	CURRENT FUND	APPROPRIATED FUNDS	TOTAL
REVENUE AND OTHER ADDITIONS:			
Product Sales	28,783,733	0	28,783,733
Restricted Grants & Contracts	4,286,191	0	4,286,191
State Appropriations/DPH	1,000,000	790,600	1,790,600
Royalty Fees and Interest	17,521,197	0	17,521,197
Recovery of Indirect Costs	524,788	0	524,788
Other Income	2,626,000	0	2,626,000
	<hr/>		
Total Revenue and Other Additions	54,741,909	790,600	55,532,509
<hr/>			
EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	18,563,880	403,085	18,966,965
Fringe Benefits	5,817,873	128,408	5,946,281
Supplies and Services	28,089,656	259,107	28,348,763
Depreciation	1,968,533	0	1,968,533
	<hr/>		
Total Expenditures and Other Deductions	54,439,942	790,600	55,230,542
<hr/>			
Net Increase Before Transfers	301,967	0	301,967
Nonmandatory Transfers			
Transfers	0	0	0
	<hr/>		
Total Transfers	0	0	0
<hr/>			
NET INCREASE FOR THE YEAR	301,967	0	301,967
<hr/>			
Fund Balances at Beginning of Year (7/1/18)	61,652,829	0	61,652,829
<hr/>			
FUND BALANCES AT END OF YEAR	61,954,796	0	61,954,796
<hr/>			

University of Massachusetts Biologic Laboratories

**Balance Sheet
As of June 30, 2019
(Unaudited)**

	CURRENT FUND FY19	PLANT FUND FY19	TOTAL FY19
Assets			
Cash	32,211,846	(2,198,343)	30,013,503
Accounts Receivable	4,454,797	0	4,454,797
Inventory	12,944,742	0	12,944,742
Prepaid Expenses	1,831,853	0	1,831,853
Buildings & Equipment	0	15,144,155	15,144,155
Other Assets	0	0	0
Total Assets	51,443,238	12,945,812	64,389,050
Liabilities			
Accounts Payable	1,441,598	0	1,441,598
Employee-Related Accruals	421,386	0	421,386
Other Liabilities	0	571,270	571,270
Total Liabilities	1,862,984	571,270	2,434,254
Fund Balances	49,580,254	12,374,542	61,954,796
Total Liabilities and Fund Balance	51,443,238	12,945,812	64,389,050

Financial Plans

University of Massachusetts Biologic Laboratories
Statement of Revenues, Expenditures and Other Changes
For the Period July 1, 2019 Through June 30, 2020
(Unaudited)

	CURRENT FUND	APPROPRIATED FUNDS	TOTAL
REVENUE AND OTHER ADDITIONS:			
Product Sales	33,531,574	0	33,531,574
Restricted Grants & Contracts	7,808,000	0	7,808,000
State Appropriations/DPH	0	516,000	516,000
Royalty Fees and Interest	18,795,854	0	18,795,854
Recovery of Indirect Costs	1,156,000	0	1,156,000
Other Income	(400,000)	0	(400,000)
	<hr/>		
Total Revenue and Other Additions	60,891,428	516,000	61,407,428
<hr/>			
EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	21,073,129	0	21,073,129
Fringe Benefits	6,711,301	0	6,711,301
Supplies and Services	30,728,909	0	30,728,909
Depreciation	0	0	0
	<hr/>		
Total Expenditures and Other Deductions	58,513,339	0	58,513,339
	<hr/>		
Net Increase/(Decrease) Before Transfers	2,378,089	516,000	2,894,089
<hr/>			
Nonmandatory Transfers			
Transfers	0	0	0
	<hr/>		
Total Transfers	0	0	0
	<hr/>		
Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			
<hr/>			
NET INCREASE(DECREASE) FOR THE YEAR	2,378,089	0	2,894,089
<hr/>			
Fund Balances at Beginning of Year (7/1/19)	61,954,796	0	61,954,796
	<hr/>		
FUND BALANCES AT END OF YEAR	64,332,885	0	64,848,885
	<hr/>		

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 FUND</u>	<u>APPROPRIATED FUNDS</u>	<u>TOTAL</u>
REVENUE AND OTHER ADDITIONS:			
Product Sales	35,306,863	0	35,306,863
Restricted Grants & Contracts	8,125,000	0	8,125,000
State Appropriations/DPH	0	516,000	516,000
Royalty Fees and Interest	18,795,750	0	18,795,750
Recovery of Indirect Costs	540,000	0	540,000
Other Income	(400,000)	0	(400,000)
	<hr/>		
Total Revenue and Other Additions	62,367,614	516,000	62,883,614
EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	22,296,792	0	22,296,792
Fringe Benefits	7,085,207	0	7,085,207
Supplies and Services	30,461,901	0	30,461,901
	<hr/>		
Total Expenditures and Other Deductions	59,843,900	0	59,843,900
Net Increase/(Decrease) Before Transfers	2,523,714	516,000	3,039,714
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	2,523,714	0	3,039,714
Fund Balances at Beginning of Year (7/1/20)	64,848,885	0	64,848,885
	<hr/>		
FUND BALANCES AT END OF YEAR	67,372,599	0	67,888,599

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

	<u>CURRENT FUND</u>	<u>APPROPRIATED FUNDS</u>	<u>TOTAL</u>
REVENUE AND OTHER ADDITIONS:			
Product Sales	36,470,535	0	36,470,535
Restricted Grants & Contracts	8,458,125	0	8,458,125
State Appropriations/DPH	0	516,000	516,000
Royalty Fees and Interest	18,795,644	0	18,795,644
Recovery of Indirect Costs	562,140	0	562,140
Other Income	(400,000)	0	(400,000)
Total Revenue and Other Additions	63,886,444	516,000	64,402,444
EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	22,791,490	0	22,791,490
Fringe Benefits	7,268,486	0	7,268,486
Supplies and Services	31,151,544	0	31,151,544
Total Expenditures and Other Deductions	61,211,520	0	61,211,520
Net Increase/(Decrease) Before Transfers	2,674,924	516,000	3,190,924
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	2,674,924	0	3,190,924
Fund Balances at Beginning of Year (7/1/21)	64,848,885	0	64,848,885
FUND BALANCES AT END OF YEAR	67,523,809	0	68,039,809