



October 1, 2018

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-second 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,

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

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

**A REPORT OF THE ACTIVITIES OF MASSBIOLOGICS
FISCAL YEAR 2018**

AS REQUIRED BY CHAPTER 75, SECTION 43(F)

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

&

CLERK OF THE SENATE

October 1, 2018

BY

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

TABLE OF CONTENTS

1. INTRODUCTION.....	3
2. PRIOR FISCAL YEAR (FY18) 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	5
e. Revenues, expenditures, assets and liabilities	6
f. FY18 Statement of Revenues, Expenditures and Other Changes	8
g. FY18 Balance Sheet.....	9
3. FINANCIAL PLANS.....	10
a. FY19 Projected Statement of Revenues, Expenditures and Other Changes	11
b. FY20 Projected Statement of Revenues, Expenditures and Other Changes	12
c. FY21 Projected Statement of Revenues, Expenditures and Other Changes	13

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-second year of such annual report.

The following sections provide the required information as follows:

Part 2, Prior Fiscal Year (FY18) 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) FY18 Statement of Revenues and Expenditures and Other Changes and (2) FY18 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 (FY18) INFORMATION

This section of the report presents the specific information indicated in the legislation related to the prior fiscal year (FY18: July 1, 2017 - June 30, 2018). This is the twenty-second 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 FY18:

C. difficile mAb and Uses Thereof

- 1) 07/26/2017 Europe EP Patent No. 2857418
- 2) 03/20/2018 Brazil Patent No. PI 0507433-9
- 3) 04/06/2018 Hong Kong Patent No. 1208873B

b. Agreements entered into

MassBiologics entered into a non-exclusive license agreement with Advec Inc. for the use of cells in protein production February 8, 2018.

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

- 1) Emory University of Maryland for research into cancer therapeutic, effective February 2, 2018.
- 2) Antigen Discovery Inc., for research into novel ETEC therapeutics, January 30, 2018.
- 3) St. George's University of London for research into ETEC therapeutics effective May 18, 2018.
- 4) Duke University for studies into ETEC, for research in anti-inflammatory therapeutics effective April 25, 2018.

MassBiologics' contract development and manufacturing services enjoyed continued growth in FY18. Highlights include: addition of 2 new clients utilizing services originating in the Mattapan Facility and 1 new client for the South Coast Vector Manufacturing Center. One hundred and six new service agreements were executed in FY18 generating \$16.5M in sales. CMO revenue recognized in FY18 was \$18.5M.

c. Grants and Contracts Awarded

DARPA – A no cost extension was received on Award of \$11,411,276 from Defense ADV Research Projects Agency through June 30, 2018. \$411,488 of funding was received in FY18.

Gates Foundation – Award of \$2,226,750 was received from Bill and Melinda Gates Foundation effective May 4, 2017 through February 28, 2019. \$1,196,111 of funding was received in FY18.

U24 Grant – Award of \$8,645,123 was received from NIH-Nat'l Inst. of Allergy & Infectious Disease effective September 29, 2016 through May 31, 2021. \$1,379,382 of funding was received in FY18.

R24 Grant - Award of \$2,770,175 was received from National Institutes of Health effective January 1, 2016 through November 30, 2019. \$652,827 of funding was received in FY18.

NIH Grant – A no cost extension was received on Award of \$1,160,228 from NIH-Nat'l Inst. of Allergy & Infectious Disease through April 30, 2018. An additional Award of \$56,133 was received. \$65,861 of funding was received in FY18.

NIH Contract - Award of \$459,288 was received from NIH-Nat'l Inst. of Allergy & Infectious Disease effective September 20, 2015 through August 31, 2017. \$7,092 of funding was received in FY18.

CTR Advancing Translational Sciences – Award of \$288,262 was received from NIH-Nat'l Ctr Advancing Transitional Sciences effective August 14, 2015 through March 31, 2019. \$48,694 of funding was received in FY18.

CDC Contract – Award of \$228,946 was received from Antigen Pharmaceuticals, Inc. effective September 30, 2015 through September 29, 2017. \$69,040 of funding was received in FY18.

UCSF Grant – Award of \$675,692 was received from University of California San Francisco effective July 16, 2016 through June 30, 2021. \$59,419 of funding was received in FY18.

MGH Grant – An award of \$257,418 was received from Massachusetts General Hospital effective December 1, 2016 through October 31, 2018. \$61,878 of funding was received in FY18.

Voyager – Award of \$125,000 was received from Voyager Therapeutics effective December 1, 2016 through October 31, 2018. \$7,256 of funding was received in FY18.

d. Status of existing agreements, royalties and other benefits

MassBiologics had the following major existing agreements in FY18.

Bristol-Meyers Squibb, formerly Medarex - a collaborative development agreement signed April 17, 2002 with a public company (Medarex) has led to discovery of a several antibodies. Commercial licenses are in place that grant MassBiologics commercialization rights to these antibodies, including for the treatment of rabies, C. Difficile (“CDiff”), Lyme, and ETEC. The Materials Cooperative Research and Development Agreement (M-CRADA) that was entered into January 30, 2004 with the CDC for Rabies was extended until January 30, 2006. Subsequently, that agreement evolved into an Inter-institutional Agreement that was executed in August 2005.

Merck Exclusive License Agreement April 20, 2009 for antibodies against C. Difficile. This agreement remains in place in support of continued clinical development of MassBiologics’ proprietary CDiff antibodies.

Serum Institute of India License and Collaboration Agreement 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 and Canada, effective July 1, 2015 as extended.

Voyager Therapeutics Inc. – Strategic Collaboration Agreement for development and manufacturing of adeno associated virus (AAV) products, effective October 20, 2014.

Life Technologies Corporation – Cell Line Services License agreement effective December 19, 2014; Commercial Production License effective May 1, 2015; authorizes use of certain materials to support internal research and for use in services provided to external parties.

Sale of Reagents: Reagents are 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) FY18 Statement of Revenues and Expenditures and Other Charges and (2) FY18 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 (“DPH” is the Department of Public Health) represents the DPH appropriated fund support of the effort at the Biologic Laboratories of \$797,126. 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 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 FY18, the plant fund continued to also be used to conclude the new facility expenses.

The core activities of MassBiologics remained consistent through FY18. 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 will be repaid over the next five years.

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, 2017 Through June 30, 2018
(Unaudited)

	<u>CURRENT FUND</u>	<u>APPROPRIATED FUNDS</u>	<u>TOTAL</u>
REVENUE AND OTHER ADDITIONS:			
Product Sales	37,752,620	0	37,752,620
Restricted Grants & Contracts	3,959,047	0	3,959,047
State Appropriations/DPH	0	797,126	797,126
Royalty Fees and Interest	19,789,481	0	19,789,481
Recovery of Indirect Costs	511,498	0	511,498
Other Income	997,725	0	997,725
	<hr/>		
Total Revenue and Other Additions	63,010,371	797,126	63,807,497
<hr/>			
EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	18,152,161	405,732	18,557,893
Fringe Benefits	5,663,884	129,249	5,793,134
Supplies and Services	31,157,718	262,145	31,419,863
Depreciation	1,849,815	0	1,849,815
	<hr/>		
Total Expenditures and Other Deductions	56,823,578	797,126	57,620,704
	<hr/>		
Net Increase/(Decrease) Before Transfers	6,186,793	0	6,186,793
Nonmandatory Transfers			
Transfers	2,340,948	0	2,340,948
	<hr/>		
Total Transfers	2,340,948	0	2,340,948
	<hr/>		
Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			
NET INCREASE(DECREASE) FOR THE YEAR	8,527,741	0	8,527,741
	<hr/>		
Fund Balances at Beginning of Year (7/1/17)	53,125,089		53,125,089
	<hr/>		
FUND BALANCES AT END OF YEAR	61,652,829	0	61,652,829
	<hr/>		

University of Massachusetts Biologic Laboratories
Balance Sheet
As of June 30, 2018
(Unaudited)

	CURRENT FUND FY18	PLANT FUND FY18	TOTAL FY18
Assets			
Cash	37,209,957	55,127	37,265,084
Accounts Receivable	3,429,371	0	3,429,371
Inventory	9,664,869	0	9,664,869
Prepaid Expenses	965,241	0	965,241
Buildings & Equipment	0	15,267,807	15,267,807
Other Assets	0	0	0
Total Assets	51,269,438	15,322,934	66,592,372
Liabilities			
Accounts Payable	2,583,648	882,612	3,466,259
Employee-Related Accruals	396,447	0	396,447
Other Liabilities	0	1,076,836	1,076,836
Total Liabilities	2,980,095	1,959,448	4,939,543
Fund Balances	48,289,343	13,363,486	61,652,829
Total Liabilities and Fund Balance	51,269,438	15,322,934	66,592,372

FINANCIAL PLANS

University of Massachusetts Biologic Laboratories
Statement of Revenues, Expenditures and Other Changes
For the Period July 1, 2018 Through June 30, 2019
(Unaudited)

	<u>CURRENT FUND</u>	<u>APPROPRIATED FUNDS</u>	<u>TOTAL</u>
REVENUE AND OTHER ADDITIONS:			
Product Sales	32,399,584	0	32,399,584
Restricted Grants & Contracts	7,808,000	0	7,808,000
State Appropriations/DPH	0	516,000	516,000
Royalty Fees and Interest	18,795,955	0	18,795,955
Recovery of Indirect Costs	1,156,000	0	1,156,000
Other Income	(400,000)	0	(400,000)
	<hr/>		
Total Revenue and Other Additions	59,759,540	516,000	60,275,540
EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	20,689,146	0	20,689,146
Fringe Benefits	6,588,844	0	6,588,844
Supplies and Services	30,241,245	0	30,241,245
Depreciation	0	0	0
	<hr/>		
Total Expenditures and Other Deductions	57,519,235	0	57,519,235
Net Increase/(Decrease) Before Transfers	2,240,305	516,000	2,756,305
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	2,240,305	0	2,756,305
Fund Balances at Beginning of Year (7/1/18)	61,652,829	0	61,652,829
	<hr/>		
FUND BALANCES AT END OF YEAR	63,893,134	0	64,409,134

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

	<u>CURRENT FUND</u>	<u>APPROPRIATED FUNDS</u>	<u>TOTAL</u>
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)
Total Revenue and Other Additions	60,891,428	516,000	61,407,428
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
Total Expenditures and Other Deductions	58,513,339	0	58,513,339
Net Increase/(Decrease) Before Transfers	2,378,089	516,000	2,894,089
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	2,378,089	0	2,894,089
Fund Balances at Beginning of Year (7/1/19)	64,409,134	0	64,409,134
FUND BALANCES AT END OF YEAR	66,787,223	0	67,303,223

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
Depreciation	0	0	0
	<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)	67,303,223	0	67,303,223
	<hr/>		
FUND BALANCES AT END OF YEAR	69,826,937	0	70,342,937