

Honorable Timothy Carroll
Clerk of the House of Representatives
Room 145
State House
Boston, MA 02133

Oct. 1, 2025

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

Dear Mr. Carroll 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 the University of Massachusetts laboratories within ninety days after the end of the fiscal year.” Fiscal Year 2025 is the twenty-eighth year of such annual reports required by the legislation, which transitioned the biologic laboratories of the state laboratory institute from the Department of Public Health to the University of Massachusetts. This report may be supplemented as necessary prior to the filing of the Fiscal Year 2026 report.

If you have any questions, please contact Executive Vice Chancellor John C. Lindstedt, UMass Chan Medical School, 55 Lake Ave. North, Worcester, MA 01655, (508) 856-2198.

Sincerely,



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



John C. Lindstedt
Executive Vice Chancellor, A&F
University of Massachusetts
Chan Medical School

A REPORT OF THE ACTIVITIES OF MASSBIOLOGICS FISCAL YEAR 2025

AS REQUIRED BY CHAPTER 75, SECTION 43(F)

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

Oct. 1, 2025

BY MASSBIOLOGICS of the
UNIVERSITY OF MASSACHUSETTS
CHAN MEDICAL SCHOOL



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I. 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-eighth year of such annual reports.

The following sections provide the required information as follows:

Part 2, Prior Fiscal Year (FY25) Information, as indicated by legislation, describes the patents, licenses and agreements entered into; status of existing agreements; royalties and other benefits; and expenditures, current assets and liabilities. This section includes two schedules: (1) FY25 Statement of Revenues and Expenditures and Other Changes and (2) FY25 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 (FY25) INFORMATION

This section of the report presents the specific information indicated in the legislation related to the prior fiscal year (FY25: July 1, 2024–June 30, 2025). This is the twenty-eighth full year in which MassBiologics has operated within the University of Massachusetts. The effective date of the transfer to the University of Massachusetts was Jan. 1, 1997.

a. Patents and Licensing

MassBiologics had three patents issued in FY25:

- 1) Human Monoclonal Antibodies Against *Clostridium Difficile* Toxins 7/16/2024
Netherlands Patent Number 2857418.
- 2) Monoclonal Antibodies to Dimeric and Secretory IgA and Uses Thereof 12/17/2024
United States 12168699.
- 3) Cross-protective nanobodies (VHHs) and their derivatives against colonization factor antigens of Enterotoxigenic *Escherichia coli* (ETEC) and their uses 10/1/2024 United States 12103963.

b. Collaboration and CDMO Service Agreements entered into:

MassBiologics Contract Development and Manufacturing Services in FY25 include:

Three existing clients continuing their production programs. Three new project specific service agreements were executed in FY25. Total CDMO revenue recognized in FY25 was \$13M.

c. Status of existing agreements, royalties and other benefits/challenges

MassBiologics had the following major existing agreements in FY25.

Medimmune (formerly Molecular Vaccines), license for Synagis, a therapeutic for respiratory syncytial virus (RSV) signed Aug, 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. We are aware of several competing products now on the market that also treat RSV, and accordingly, we are monitoring the potential impact of these competing products on our future royalty revenues from Synagis sales.

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) Nov. 8, 2006. Saol Therapeutics acquired CytoGam rights from CSL Behring Aug. 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.

A Materials Cooperative Research and Development Agreement (M-CRADA) was entered on Jan. 30, 2004, with the CDC for rabies and then extended until Jan. 30, 2006. Subsequently, that agreement evolved into an Inter-Institutional Agreement that 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 Sept. 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. This agreement was terminated in 2025 and will be excluded from subsequent annual reports. With respect to same, we have consulted with the commonwealth's Department of Public Health with respect to ceasing Td manufacturing due to the widespread use of the more effective Tdap vaccine, and the DPH advised that they, too, are moving to the Tdap product because of that drug's advantages and at an overall cost savings.

Beginning with the onset of the Covid-19 pandemic and continuing through this FY25, we have been studying the long-term sustainability and financial challenges of the MassBiologics manufacturing operations, as now similarly experienced by other biomanufacturing businesses in the commonwealth, and in response to same, we have engaged outside consultants, including William Blair and TKD Solutions, to assist us in better understanding the current marketplace and developing a new strategic plan for same.

Commencing in FY24 and continuing into this FY25, our MassBiologics and UMass Chan facilities, in Mattapan and Fall River, respectively, underwent certain regulatory inspections. These activities were successful with the approval of PTC client product Upstaza/Kebilidi from the following regulatory agencies: FDA, HPRA, ANVISA, Israel and Tawain.

During this FY25, we have taken certain staff actions and utilized the services of consultants to ensure we are able to fulfill our current contractual obligations.

Historically, MBL's operations have been supported principally by revenues from the sales of Td vaccine, milestone and royalty payments (mostly from sales of Synagis to treat RSV), and most recently from a contract with PTC (to manufacture the drug Upstanza). However, this current year, MBL was caused to discontinue the manufacturing of Td, as that product has been replaced in the main commercial markets by a more effective and less costly product, Tdap. In addition, and as stated above, competition from other RSV-treatment drugs is expected to adversely impact sales of Synagis, thereby decreasing the amount of royalties received from same. In addition, there have also been recent developments with respect to the nature of the PTC contract that might impact the long-term future of that revenue stream. All these factors, in conjunction with a severe downturn in the life sciences and gene therapy markets, a marked reduction in venture capital and grant funded investment in same, and a need for MBL to consider essential but very costly capital upgrades and improvements has resulted in MBL continuing to experience significant financial difficulties.

As referenced in the Land Disposition Agreements attendant to the development and construction of the two (2) MassBiologics buildings in Mattapan, we regularly met with the local Citizens Advisory Committee and fully met all financial obligations related to same.

d. Revenues, expenditures, assets and liabilities

On the pages that follow, please find two schedules: (1) FY25 Statement of Revenues and Expenditures and Other Charges and (2) FY25 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:

- 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 FY25. 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.

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, the University of Massachusetts President's Office, in partnership with UMass Chan, determined that the previously constructed Massachusetts Accelerator for Biomanufacturing (MAB) facility (located at 1240 Innovation Way in Fall River, MA), 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 UMass Chan Medical School (UMass Chan). Grants totaling \$10M from theMLSC and MassWorks were invested in the facility 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.

UMass Chan 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 payment.

e. MassBiologics Advisory Board

MassBiologics' enabling legislation [Chapter 334 of the Acts of 1996] that effectively transferred the oversight and operation of MassBiologics to the University of Massachusetts included a provision that called for the establishment of an advisory board to “advise the president and the board of trustees of the university with respect to the operation of the biologic laboratories.”

The statute sets certain parameters on the Advisory Board's composition by stipulating the following membership conditions: (1) the commissioner of public health or designee; (2) the director of the childhood immunization program of the Department of Public Health; (3) the dean of the Medical School of the University or designee; and (4) the dean of the School of Public Health of the University or designee. In addition to the four *ex officio* positions listed above, the statute further stipulates that the president of the University has the authority to select three to five other members to the Advisory Board, so long as the University appointments include at least one “consumer” and one “practicing pediatrician.”

In FY25, the MassBiologics Advisory Board's membership was reconstituted and strengthened with the addition of four new members. The Massachusetts DPH Commissioner identified two senior colleagues to join the Advisory Board: Jessica Zeidman, MD, Deputy Commissioner and Chief Medical Officer, DPH; and Angela Fowler, MD, MPH, Associate Medical Director for Vaccine Preventable Diseases, DPH. Drs. Zeidman and Fowler occupy DPH's *two ex officio* seats on the Advisory Board. In addition, the University approved the appointment of two other individuals to fill the consumer role stipulated in the enabling legislation: Katherine Luzuriaga, MD, Vice Provost for Research, *UMass Memorial Health Care Chair in Biomedical Research*, Professor of Molecular Medicine, Pediatrics and Medicine, and Director of the UMass Center for Clinical and Translational Science, UMass Chan Medical School; and Gregory Volturo, MD, Chair and Professor of Emergency Medicine and the *Richard V. Aghababian, MD'74 Chair in Emergency Medicine* at UMass Chan Medical School, who is serving in his second term on the Public Health Council.

With these value-added additions, the MassBiologics Advisory Board's membership includes the following:

Michael F. Collins, MD (*Ex Officio*)

Senior Vice President for the Health Sciences, University of Massachusetts; Professor of Medicine and Quantitative Health Sciences & Chancellor, UMass Chan Medical School

Terence R. Flotte, MD (Practicing Pediatrician)

Executive Deputy Chancellor, Provost and Chief Research Officer, UMass Chan Medical School; *The Celia and Isaac Haidak Professor of Medical Education & Dean, T.H. Chan School of Medicine*

Anna Maria Siega-Riz, PhD (*Ex Officio*)

Dean, School of Public Health and Health Sciences, UMass Amherst

Jessica Zeidman, MD (*Ex Officio*)

Deputy Commissioner and Chief Medical Officer, Massachusetts Department of Public Health

Angela Fowler, MD, MPH (*Ex Officio*)

Associate Medical Director for Vaccine Preventable Diseases, Massachusetts Department of Public Health

Katherine Luzuriaga, MD (Consumer)

Vice Provost for Research; *UMass Memorial Health Care Chair in Biomedical Research*; Professor of Molecular Medicine, Pediatrics and Medicine; Director of the UMass Center for Clinical and Translational Science, UMass Chan Medical School

Gregory Volturo, MD (Consumer)

Professor and Chair of Emergency Medicine; *Richard V. Aghababian, MD'74 Chair in Emergency Medicine*, UMass Chan Medical School

The Advisory Board convened for a formal meeting on April 15, 2025, during which the members received updates on the gene therapy market, MassBiologics operations and budget projections for FY25 and FY26. The Advisory Board will meet again on Sept. 30, 2025.

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	12,857,908	0	12,857,908
Royalty Fees and Interest	16,161,567	0	16,161,567
Other Income	605,099	0	605,099
Total Revenue and Other Additions	29,624,574	0	29,624,574
EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	7,683,215	0	7,683,215
Fringe Benefits	1,900,892	0	1,900,892
Supplies and Services	28,072,254	0	28,072,254
Depreciation	1,518,811	0	1,518,811
Total Expenditures and Other Deductions	39,175,172	0	39,175,172
Net Increase/(Decrease) Before Transfers	(9,550,598)	0	(9,550,598)
Nonmandatory Transfers			
Transfers	(147,158)	0	(147,158)
Total Transfers	(147,158)	0	(147,158)
Other Changes			
Excess of Restricted Receipts over Transfers to Revenue	0	0	0
NET INCREASE(DECREASE) FOR THE YEAR			
	(9,697,756)	0	(9,697,756)
Fund Balances at Beginning of Year (7/1/24)	10,687,863	0	10,687,863
FUND BALANCES AT END OF YEAR	990,107	0	990,107

University of Massachusetts Biologic Laboratories

Balance Sheet

As of June 30, 2025

(Unaudited)

	CURRENT FUND FY25	PLANT FUND FY25	TOTAL FY25
Assets			
Cash	(1,765,935)	0	(1,765,935)
Accounts Receivable	5,499,322	0	5,499,322
Prepaid Expenses	6,995,575	0	6,995,575
Buildings & Equipment	0	8,450,602	8,450,602
Total Assets	10,728,962	8,450,602	19,179,564
Liabilities			
Accounts Payable	4,138,118	0	4,138,118
Employee-Related Accruals	518,545	0	518,545
Other Liabilities	13,532,794	0	13,532,794
Total Liabilities	18,189,456	0	18,189,456
Fund Balances	(7,460,494)	8,450,602	990,107
Total Liabilities and Fund Balance	10,728,962	8,450,602	19,179,564

Financial Plans

University of Massachusetts Biologic Laboratories Summarized Projected Revenues and Expenditures For the Fiscal Years Ending June 30, 2026 through June 30, 2030

(Unaudited)

Budget:

- Each year, the University develops an annual operating budget that is presented to the Board of Trustees in June.
- The FY26 budget in this report reflects that operating budget presented in June 2025.
- Additionally, each quarter, a year end projection is developed reflective of actuals plus assumptions for the remainder of the fiscal year.
- The first quarter projection will be completed after the close of Q1 (9/30/25) and presented to the Board of Trustees in December.
- The FY26 projection will provide an overall update based on actuals plus more current assumptions and is subject to change what is presented in this report.

Forecast:

- Each year, the University develops a 5-year financial forecast that is typically presented to the Board of Trustees in December
- The FY27-30 forecast in this report reflects the forecast presented in December 2024.
- Currently, the forecast is being refreshed and will be presented to the board in December 2025
- This refresh will be based upon more current actuals and assumptions therefore the forecast is subject to change what is presented in this report.

Both the Quarterly Projection and 5-Year Forecast are elements provided to the Legislature as required by line item 7100-0200 in a report known as the Annual Legislative Report.

<i>\$ in thousands</i>	Budget FY26	Forecast			
		FY27	FY28	FY29	FY30
Revenue	24,636	31,227	32,008	32,808	33,629
Expenses	34,317	36,713	38,371	39,330	40,313
Surplus / (Deficit)	(9,681)	(5,486)	(6,363)	(6,522)	(6,684)