

March 5, 2025

The Honorable Joni Ernst  
Chair, Senate Committee on Small Business and Entrepreneurship  
United States Senate  
Washington, DC 20510

The Honorable Ed Markey  
Ranking Member, Senate Committee on Small Business and Entrepreneurship  
United States Senate  
Washington, DC 20510

**RE: Massachusetts Biotechnology Council (MassBio) Testimony to the Senate Committee on Small Business and Entrepreneurship: “Golden Age of American Innovation: Reforming SBIR-STTR for the 21st Century”**

Dear Chair Ernst and Ranking Member Markey:

On behalf of the Massachusetts Biotechnology Council (MassBio) and our more than 1,700 member companies, I write to express our strong support for the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. These programs are essential to fostering early-stage biotechnology innovation. Reauthorization of the program is essential in ensuring that startups to develop groundbreaking therapies, medical devices, and technologies that improve patient outcomes and strengthen U.S. global leadership in life sciences. We applaud the work by you and the Committee in identifying opportunities to modernize and improve SBIR and STTR programs for the 21<sup>st</sup> century, and we urge you to prioritize reforms that enhance program accessibility, efficiency, and effectiveness for biotech entrepreneurs.

The biotechnology sector is uniquely capital-intensive, requiring more than a decade of research, clinical trials, and regulatory approvals before products reach patients. Unlike many other industries, early-stage biotech companies often struggle to secure private investment due to the high-risk nature of their research. The SBIR and STTR programs provide critical non-dilutive funding that enables these startups to pursue transformative scientific discoveries that might not otherwise attract early-stage capital.

Consider, for example, Alzheimer’s disease. Alzheimer’s is a progressive neurological disorder that affects memory, thinking, and behavior and greatly impacts quality of life. Recent estimates suggest that more than 6.9 million Americans – about 1 in every 9 over the age of 65 – have Alzheimer’s disease.<sup>1</sup> These numbers expected to grow over the coming decades. Fortunately, Massachusetts-based companies are on the frontlines in the development of treatments to slow,

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<sup>1</sup> Alzheimer’s Association 2024 Facts and Figures; <https://www.alz.org/getmedia/76e51bb6-c003-4d84-8019-e0779d8c4e8d/alzheimers-facts-and-figures.pdf>

reduce impacts, and possibly even cure Alzheimer's disease – and the SBIR program is helping make that possible. Since 2020 alone, more than 30 Massachusetts-based companies have received SBIR grants to diagnose, prevent, or treat Alzheimer's.<sup>2</sup>

These grants have supported a diverse range of projects, from the development of novel therapeutics targeting the mechanisms responsible for the development of Alzheimer's, to advanced diagnostic tools leveraging MRI technology, machine learning, and blood-based biomarkers. The grants have also enabled the creation of cutting-edge assistive technologies, such as autonomous robots for fall detection and digital therapeutics aimed at reducing Alzheimer's risk. Additionally, funding for projects focusing on early identification of at-risk individuals, cognitive frailty monitoring, and brain imaging advancements are helping contribute to a more comprehensive approach to tackling Alzheimer's disease. By fostering groundbreaking research across multiple disciplines, SBIR funding is empowering small businesses to drive meaningful progress in understanding and combating this devastating condition.

MassBio recognizes the vital role that SBIR and STTR play in supporting early-stage biotech companies and driving scientific innovation toward treating diseases like Alzheimer's.

Understanding the importance of these programs to our members, we recently conducted a survey to assess their impact and identify opportunities for improvement of the program. The survey, conducted in late 2024, gathered insights from companies at the forefront of scientific discovery. The majority of respondents were from companies less than 10 years old and with fewer than 25 employees. Their responses reinforced the significance of SBIR/STTR funding in enabling groundbreaking research and the critical importance in ensuring the programs are reauthorized in a timely fashion. However, in response to questions asking how the SBIR/STTR programs could be improved, several common themes emerged among opportunities for reform:

### **Streamlining the Application and Award Process:**

Respondents highlighted that the lengthy and complex application process presents a significant challenge, often making it difficult to plan for funding. The National Academies 2022 assessment of SBIR and STTR programs at NIH similarly found that the review timeline is out of alignment with the needs of innovative small businesses.<sup>3</sup> We strongly support recommendations to streamline the process and ensure award decisions are communicated within 90 days of the application deadline.

### **Reducing Administrative Burden:**

Respondents reported that navigating post-award compliance processes is cumbersome and nearly necessitates a full-time administrator. These concerns align with the findings of the SBA

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<sup>2</sup> SBIR Award Data;

[https://legacy.www.sbir.gov/sbirsearch/award/all/alzheimer%27s?f%5B0%5D=im\\_field\\_state%3A105829&f%5B1%5D=itm\\_field\\_award\\_yr%3A2022&f%5B2%5D=itm\\_field\\_award\\_yr%3A2023&f%5B3%5D=itm\\_field\\_award\\_yr%3A2021&f%5B4%5D=itm\\_field\\_award\\_yr%3A2020&f%5B5%5D=im\\_field\\_program%3A105791](https://legacy.www.sbir.gov/sbirsearch/award/all/alzheimer%27s?f%5B0%5D=im_field_state%3A105829&f%5B1%5D=itm_field_award_yr%3A2022&f%5B2%5D=itm_field_award_yr%3A2023&f%5B3%5D=itm_field_award_yr%3A2021&f%5B4%5D=itm_field_award_yr%3A2020&f%5B5%5D=im_field_program%3A105791)

<sup>3</sup> National Academies, Assessment of the SBIR and STTR Programs at the National Institutes of Health (2022); <https://nap.nationalacademies.org/catalog/26376/assessment-of-the-sbir-and-sttr-programs-at-the-national-institutes-of-health>

Invention, Innovation, and Entrepreneurship Advisory Committee's (IIEAC) 2024 report.<sup>4</sup> The IIEAC recommended reducing administrative burdens by streamlining program forms and reporting requirements. We support IIEAC's recommendation and encourage the Committee to explore ways to simplify these processes to better support small businesses.

### **Addressing the Impact of R&D Tax Amortization:**

The mandatory amortization of R&D expenses, implemented in 2022, has placed an undue financial burden on pre-revenue biotech companies receiving SBIR funding. This policy disproportionately affects small businesses in our industry, undermining the very innovation that SBIR is designed to support. MassBio, along with other state biosciences associations, continues to advocate for the restoration of full R&D expensing to ensure that small biotech firms can continue driving scientific breakthroughs without facing unintended financial hardship.<sup>5</sup>

Finally, we recognize that the long-term success of the SBIR program requires efforts to improve the programs structure for companies as well as thoughtful improvements to better align funding with the program's core mission – supporting small businesses in developing innovative technologies that lead to commercialization. We understand concerns that SBIR award data indicates that across some agencies a portion of funding may be concentrated among a small group of companies who receive awards for years without demonstrating meaningful commercialization outcomes. From our experience, MassBio believes SBIR has served as an investment in emerging biotechnologies, rather than a perpetual funding source. Establishing clear expectations for progress toward commercial viability will help to ensure that SBIR funding continues to fuel innovation, drive economic growth, and support the development of cutting-edge solutions that meet the needs of both government and private sector markets.

We urge you to pursue timely reauthorization of the SBIR and STTR programs so biotechs in Massachusetts and across the country can continue to develop new innovations to treat patients. Additionally, we hope the Committee considers solutions to streamline the award process, reduce administrative burdens, and enhance effectiveness of the award dollars to ensure the programs remain a powerful tool for advancing scientific discovery, job creation, and global competitiveness in biotechnology.

MassBio appreciates your leadership and commitment to fostering innovation through the SBIR and STTR programs. We welcome the opportunity to further discuss the program's critical role in the biotech sector and how reforms can maximize its impact for the next generation of entrepreneurs.

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<sup>4</sup> SBA Invention, Innovation, and Entrepreneurship Advisory Committee (IIEAC), Enhancing U.S. Economic Competitiveness Through Support for Small Businesses and Innovators FY2024 Report; [https://www.sba.gov/sites/default/files/2025-02/Invention%2C%20Innovation%2C%20and%20Entrepreneurship%20Advisory%20Committee%20Report\\_0.pdf](https://www.sba.gov/sites/default/files/2025-02/Invention%2C%20Innovation%2C%20and%20Entrepreneurship%20Advisory%20Committee%20Report_0.pdf)

<sup>5</sup> Council of State Biosciences Associations Letter to House & Senate Leadership (March 2023); <https://www.massbio.org/wp-content/uploads/2023/11/CSBA-Tax-Amortization-Impact-March-2023-3.28.23.pdf>

Sincerely,

A handwritten signature in black ink, appearing to read 'KBO', with a stylized flourish at the end.

Kendalle Burlin O'Connell  
*President and CEO*  
*Massachusetts Biotechnology Association (MassBio)*