June 15, 2022

The Honorable Chuck Schumer
Majority Leader
United States Senate
Room S-221, The Capitol
Washington, DC 20510

The Honorable Mitch McConnell
Minority Leader
United States Senate
Room S-230, The Capitol
Washington, DC 20510

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
Room H-305, The Capitol
Washington, DC 20510

The Honorable Kevin McCarthy
Minority Leader
U.S. House of Representatives
Room S-230, The Capitol
Washington, DC 20510

Dear Majority Leader Schumer, Minority Leader McConnell, Speaker Pelosi, and Minority Leader McCarthy:

The Biotechnology Innovation Organization (BIO), BIO members and State affiliates urge immediate legislative action to repeal the harmful R&D amortization provision that went into effect earlier this year. The 2017 Tax Cuts and Jobs Act (TCJA) changed the longstanding deduction for R&D expenditures to a mandatory five-year amortization for domestic R&D and fifteen-year amortization for foreign R&D, with the effective date delayed until 2022. As has been noted by companies and industries across the economy, the R&D amortization provision will have a negative impact on American innovation and high-paying R&D jobs. For the biotechnology industry specifically, it will divert much-needed funds away from small R&D-intensive companies, potentially doing long-term damage to the development of the future treatments and ultimately limiting the pipeline of treatments and products that patients and consumers are relying on our industry to develop; technologies that help heal, fuel, and feed the world.

For this reason, legislation should be enacted to restore the expensing of R&D expenditures retroactive to January 1, 2022.

Biotechnology Innovation Organization

BIO represents approximately 1,000 members in the biotech ecosystem with a central mission – to advance public policy that supports a wide range of companies and academic research centers that are working to apply biology and technology in the energy, agriculture, manufacturing, and health sectors to improve the lives of people and the health of the planet. Consistent with this mission, BIO supports legislation that encourages investment in R&D and that removes impediments to increasing R&D.

The majority of BIO's diverse membership are research-intensive, small and large biotechnology companies working on cutting-edge innovations. This group includes many pre-revenue, human health companies that take enormous risks to develop the next generation of biomedical breakthroughs. Their discoveries will benefit millions of patients currently suffering from diseases for which there are no effective cures or treatments. In addition to commercial-

stage biotechs with expansive R&D pipelines, this group also includes start-up companies at the forefront of biotechnology in agriculture, food systems, energy, and biobased manufacturing. Over the past 25 years, these technologies have enabled large shifts in agronomic practices that have led to significant and widespread environmental and production benefits and the development of sustainable biofuels and biobased products.

R&D Has Positive Externalities

R&D has positive externalities – that is, there are spillover benefits to society from the R&D process that are not captured by the party conducting the R&D. For this reason, the United States (and other countries) have encouraged R&D investment with both tax and non-tax incentives. The elimination of R&D expensing by the TCJA is a retrograde step that undermines this policy. Maintaining the current amortization regime has the potential to do long-term damage to the economy in general and to the biotech industry, as outlined below.

R&D Amortization Jeopardizes Investment in Lengthy, Risky and Costly Biotech Projects

Developing the next generation of breakthroughs takes enormous amounts of capital. Drug development has one of the lowest success rates—less than 10%-- of any industry. It can take over 10 years and in excess of $1.4 billion to bring a single drug to market. Maintaining robust investment now is critical for ensuring sufficient products move through the pipeline and eventually succeed in coming to market a decade later. The United States has long had the most sophisticated biotech innovation ecosystem in part due to its significant investment in the early-stage biotech companies. Mandatory capitalization of R&D costs will both reduce after-tax returns for investments in R&D (making biotechnology investments relatively less attractive) and divert much needed funding away from R&D to the payment of income taxes. These adverse effects will jeopardize the development of treatments coming to market many years from now.

Critically, this provision comes into effect in an investment environment that is already extremely challenging for small biotechs. Venture Capital investment in the sector is showing signs of slowing, while biotech market indexes are down substantially more than the S&P 500. Many small biotechs are trading below cash values, and there have been significantly fewer IPOs and other financings this year. These increases in the cost of capital hit particularly hard coming at a time when interest rates are rising. The result is that many of the regular avenues for funding are closing and the need for small and mid-sized biotechs to preserve capital and rely on investment from larger companies in the industry is becoming more acute. Unfortunately, the R&D amortization provision exacerbates the funding difficulties that were already growing in the industry.

R&D Amortization Will Adversely Impact Funding of Chronic Disease As Well As Rare Disease R&D Projects

For the millions of patients waiting for new treatments for currently unmet medical needs, the biotech industry holds the promise of life improving and life-saving products. Small, innovative companies are on the forefront of meeting this need for patients, but they cannot fulfill their mission without access to vast amounts of capital. The biotech ecosystem depends in significant part upon investment by larger companies into early-stage companies, as well as investment by larger companies into their own pipeline drugs. As capital is restricted, large companies will have to assess where their restricted dollars should go. In terms of human health, this could exclude higher risk /higher development-cost treatments for diseases such as

Alzheimer's, Parkinson's, obesity, cardiovascular, diseases with significant unmet need, and other diseases. These highly prevalent, chronic diseases require large, costly, and time-consuming clinical trials. In rough terms, the larger the population a drug would treat, the larger the clinical trials required to bring it to market. Accordingly, drugs for which there is a large potential patient population also require significantly more cost and time to bring to market. The move to amortization directly threatens investment in treatments for these common diseases.

In addition, challenges already exist in developing therapeutic treatment options for rare diseases, such as small patient populations, variability in disease progression, and lack of well-established endpoints and poorly understood natural histories. TCJA already included a 50% reduction in the value of orphan drug tax credits aimed at offsetting the high clinical costs associated with rare disease research. This is coupled with the extended 15-year amortization period now required for ex-US research, which disproportionately impacts biotech companies in the rare disease space who are forced to conduct ex-US clinical trials due to small patient populations in the US alone. Amortization could further limit the breadth of research and development into rare diseases and diminish hope for the millions of rare disease patients and families who currently lack effective therapies.

Given the long development timelines, a reduction in investment by larger companies now will have lasting implications for the development of new life-saving treatments both in the short and long term. Maintaining a robust biotech ecosystem requires ensuring sufficient funding and advancement of numerous promising technologies. Other sources of funding cannot make up the void if the larger companies shift their resources or downsize their pipelines altogether.

R&D Amortization Diverts Company Funding Away from R&D

In addition to diminishing investment dollars, mandatory amortization will also directly diminish the amount of capital small companies are able to devote to research. Emerging biotechs that do not have a product on the market, do not yet have sales to generate income (*i.e.*, they are "pre-revenue"); however, they are not immune from the tax consequences of the shift to amortization, which will spread their deductions for R&D expenditures over a longer period. Both emerging and growing biotechs rely on partnerships with larger companies to help fund their research. These arrangements typically involve various payments to the emerging company, including up-front payments and payments upon the achievement of specified milestones. The payments received under these collaboration agreements may be treated as taxable income. Emerging companies typically can utilize their NOL carryforwards, generated by the immediate expensing of R&D costs, to offset some or all of this taxable income. This allows the companies to devote a greater portion of their resources to bringing their product to market faster. For many companies, the move to amortization will likely result in a tax liability because they will have smaller NOL carryforwards, diverting critical funds away from R&D. (Even for taxpayers with large NOLs, the ability to offset taxable income with the carryforwards is subject to a variety of restrictions that may not permit a complete offset of the taxable income. The required amortization will exacerbate the issue of having to pay cash taxes instead of allocating funding to R&D.) Indeed, for pure R&D companies like early-stage biotechs, this shift can dramatically impact their business model, shortening their runways, lowering valuations and siphoning off cash that could be used for purposes like employing scientists and advancing science. For commercial-stage biotechs with expanding clinical pipelines, the tax increase resulting from R&D amortization can nearly double a company's cash tax burden in the initial years of amortization.

Similarly, a company that does contract manufacturing will need to recognize the income in the year of the research while the R&D expense is amortized, resulting in a timing mismatch and creating upfront taxable income purely as a result of this tax law shift.

Thus, in many cases, this change to the tax law essentially amounts to a tax on innovation and a threat to the millions of patients relying on these companies for treatments and cures

Mandatory R&D Amortization Should Be Repealed

In short, the change to amortization will have a direct impact—in some cases, a double hit—on development of early-stage treatments. Put simply, as less dollars go into drug development, less products will advance through the pipeline. Thus, in very real terms, today's tax policies are putting tomorrow's breakthroughs at risk.

Congress needs to act now. Companies cannot wait until the end of the year for a fix. The impact of the provision is already being felt. Companies are already being forced to make estimated tax payments, and make these hard decisions about how to reallocate their resources. Compounding the problem, there is very little guidance on how to calculate the direct and indirect expenses to be capitalized, creating confusion and potential sources of conflict and additional expense down the road.

BIO urges you to immediately reverse the R&D amortization provision and include a fix in the next possible legislative vehicle. Immediate action is critical to avoid the harmful impact on R&D companies today and ensure the development of future treatments and cures for tomorrow.

Sincerely,

Biotechnology Innovation Organization (BIO)
Washington, DC

Acorda Therapeutics, Inc. (Ron Cohen, Founder, President & CEO, BIO Board Director)
Ardsley, NY

Aequor, Inc.
San Diego, CA

Alexion Pharmaceuticals, Inc.
Boston, MA

Allievex Corp. (Thomas Mathers, President & CEO, BIO Board Director)
Marblehead, MA

Alnylam Pharmaceuticals, Inc.
Cambridge, MA
Brisbane, CA

Alumis, Inc. (Martin Babler, Chairman, President & CEO, BIO Board Director)
South San Francisco, CA

Ananke Therapeutics (Julia Owens, CEO, BIO Board Director)
Cambridge, MA

Anthos Therapeutics, Inc. (John Glasspool, CEO, BIO Board Director)
Cambridge, MA

Antiva Biosciences, Inc. (Gail Maderis, President & CEO, BIO Board Director)
Brisbane, CA

Arcutis Biotherapeutics, Inc. (Frank Watanabe, President & CEO, BIO Board Director)
Westlake Village, CA

Ashvattha Therapeutics (Jeff Cleland, Chairman, President & CEO, BIO Board Director)
Redwood City, CA

Asklepios BioPharmaceutical, Inc. (AskBio) (Sheila Mikhail, Co-Founder & CEO, BIO Board Director)
Research Triangle Park, NC

Caribou Biosciences (Rachel Haurwitz, President & CEO, BIO Board Director)
Berkeley, CA

Capsida Biotherapeutics, Inc.
Thousand Oaks, CA

Cerevast Medical Inc. (Bradford Zakes, President & CEO, BIO Board Director)
Bothell, WA

Chiesi USA, Inc (Giacomo Chiesi, Head of Global Rare Diseases, BIO Board Director)
Cary, NC

Corteva Agriscience
Indianapolis, IN

Eisai, Inc
Nutley, NJ

Exelixis, Inc.
Alameda, CA

First Wave BioPharma, Inc. (James Sapirstein, Chairman, President & CEO, BIO Board Director)
Boca Raton, FL

Global Blood Therapeutics (Ted Love, President & CEO, BIO Health Section Vice Chair (Vice Chair of BIO Board))
South San Francisco, CA

Genexine, Inc (Neil Warma, CEO, BIO Board Director)
San Diego, CA and Seoul, Republic of Korea

GT Biopharma, Inc.
Brisbane, CA

Incyte Corporation
Wilmington, DE

Iolyx Therapeutics (Elizabeth Jeffords, CEO, BIO Board Director)
Menlo Park, CA

Ionis Pharmaceuticals, Inc.
Carlsbad, CA

Kezar Life Sciences, Inc.
South San Francisco, CA

Nkarta Therapeutics, Inc. (Paul Hastings, CEO, Chair of BIO Board (Chair of the BIO Health Section))
South San Francisco, CA

Ovid Therapeutics, Inc. (Jeremy Levin, Chairman & CEO, BIO Board Director)
New York, NY

Pieris Pharmaceuticals
Boston, MA

PTC Therapeutics, Inc.
South Plainfield, NJ

REGENXBIO, Inc.
Rockville, MD

Rubius Therapeutics, Inc. (Pablo Cagnoni, President & CEO, BIO Board Director)
Cambridge, MA

SAB Biotherapeutics, Inc (Eddie Sullivan, Co-Founder President & CEO, BIO Board Director)
Sioux Falls, SD

Sana Biotechnology, Inc. (Steve Harr, President & CEO, BIO Board Director)
Seattle, WA

Sanofi
Bridgewater, NJ

Sarepta Therapeutics
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Sutro Biopharma, Inc. (William Newell, CEO, BIO Board Director)
South San Francisco, CA

SynDevRx, Inc.
Cambridge, MA

Syros Pharmaceuticals, Inc. (Nancy Simonian, President & CEO, BIO Board Director)
Cambridge, MA

Tempest Therapeutics, Inc. (Stephen Brady, CEO, BIO Board Director)
South San Francisco, CA

Trevi Therapeutics, Inc. (Jennifer Good, Co-Founder, President & CEO, BIO Board Director)
New Haven, CT

UCB, Inc
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Versanis Bio (Mark Pruzanski, Chairman & CEO, BIO Board Director)
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Vertex Pharmaceuticals
Boston, MA

Arizona BioIndustry Association

Bio Nebraska

Biocom California

BioCT

BioFlorida

BioForward Wisconsin

BioKansas

BioNJ

Bioscience Association of West Virginia

BioUtah

California Life Sciences

Center for Global Health Innovation/Georgia Bio

Colorado BioScience Association
Illinois Biotechnology Innovation Organization

Indiana Health Industry Forum

Industry University Research Center, Inc.

Iowa Biotechnology Association

Louisiana BIO

Massachusetts Biotechnology Council

Medical Alley Association

MichBio

Missouri Biotechnology Association

New Mexico Biotechnology & Biomedical Association

NewYorkBio

RI Bio

Southern California Biomedical Council

South Dakota Biotech Association

Texas Healthcare & Bioscience Institute

Cc: The Honorable Ron Wyden

Chair, Senate Finance Committee

The Honorable Mike Crapo

Ranking Member, Senate Finance Committee

The Honorable Richie Neal

Chair, House Ways & Means Committee

The Honorable Kevin Brady

Ranking Member, House Ways & Means Committee