

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**AXERION THERAPEUTICS
GENERALLY CLAIMED
ALLOWABLE RECOVERY ACT
GRANT COSTS**

*Inquiries about this report may be addressed to the Office of Public Affairs at
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**Michael J. Armstrong
Regional Inspector General**

**September 2012
A-01-11-02509**

Office of Inspector General

<http://oig.hhs.gov>

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

The American Recovery and Reinvestment Act of 2009, P.L. No. 111-5 (Recovery Act), enacted on February 17, 2009, provided \$8.2 billion to the Office of the Director of the National Institutes of Health (NIH) to help stimulate the economy through the support and advancement of scientific research. Of the \$8.2 billion, the Recovery Act transferred \$7.4 billion to NIH institutes, centers, and offices and to the NIH Common Fund. In addition, the Recovery Act provided \$400 million for comparative effectiveness research. NIH allocated \$300 million of Recovery Act funding to the National Center for Research Resources for shared instrumentation and other capital equipment.

Recovery Act funds were used to award grants and cooperative agreements to research entities including nonprofit and for-profit organizations, universities, hospitals, research foundations, governments and their agencies, and occasionally individuals.

Axerion Therapeutics (the grantee), established in 2009, is a private biotechnology company focused on developing therapeutics for neurological diseases and injuries. NIH awarded the grantee a Recovery Act grant of \$3 million for research related to neurological recovery from spinal cord injury and stroke. The grant budget period is April 15, 2010, through March 31, 2013. As of March 31, 2011, the grantee had claimed \$950,844 under the grant; we reviewed the total amount claimed by the grantee.

OBJECTIVE

Our objective was to determine whether costs claimed by the grantee were allowable under the terms of the grant and applicable Federal regulations.

SUMMARY OF FINDING

The grantee claimed costs of \$950,844 that were allowable under the terms of the grant and applicable Federal regulations; however, the grantee did not account for the \$53,966 in proceeds earned from the sale of equipment that was purchased for the grant.

RECOMMENDATION

We recommend that NIH work with the grantee to account for the \$53,966 in proceeds earned from the sale of equipment.

AXERION THERAPEUTICS COMMENTS

In written comments on our draft report, the grantee did not concur with our initial recommendation that NIH recover \$53,150 that the grantee claimed in unallowable

equipment costs. The grantee stated that it had an opportunity to purchase a biologics lab, which included equipment, to conduct the research outlined in the grant award. The grantee stated that it sold pieces of equipment during 2010 that it concluded were not necessary for the research grant. Based on its review of the Federal regulations and discussions with NIH staff, the grantee stated that it concluded that the sale of this equipment did not require it to return the funds to NIH because it planned to use the funds to support its NIH grant research in the future. The grantee stated that it had determined that it would use the funds in grant year 2 by not requesting grant reimbursement from NIH once it exceeded \$2 million of expenses for grant years 1 and 2. The grantee's comments are included in their entirety as Appendix A.

OFFICE OF INSPECTOR GENERAL RESPONSE

After discussions with NIH officials, we revised our recommendation in this draft report. We originally recommended that NIH recover \$53,150 that the grantee claimed for unallowable equipment costs, but we now recommend that NIH work with the grantee to account for the \$53,966 in proceeds earned from the sale of the equipment.

NATIONAL INSTITUTES OF HEALTH COMMENTS

In written comments to our draft report, NIH concurred with our finding and recommendation. NIH's comments, excluding technical comments that we address in this report as appropriate, are included in their entirety as Appendix B.

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INTRODUCTION

BACKGROUND

The American Recovery and Reinvestment Act of 2009, P.L. No. 111-5 (Recovery Act), enacted on February 17, 2009, provided \$8.2 billion to the Office of the Director of the National Institutes of Health (NIH) to help stimulate the economy through the support and advancement of scientific research. Of the \$8.2 billion, the Recovery Act transferred \$7.4 billion to NIH institutes, centers, and offices and to the NIH Common Fund. In addition, the Recovery Act provided \$400 million for comparative effectiveness research. NIH allocated \$300 million of Recovery Act funding to the National Center for Research Resources for shared instrumentation and other capital equipment.

Recovery Act funds were used to award grants and cooperative agreements to research entities including nonprofit and for-profit organizations, universities, hospitals, research foundations, governments and their agencies, and occasionally individuals.

Federal Requirements for Grantees

The Uniform Administrative Requirements for awards and subawards that apply to commercial organizations are found at 45 CFR Part 74.

Axerion Therapeutics

Axerion Therapeutics (the grantee), established in 2009, is a commercial biotechnology company focused on developing therapeutics for neurological diseases and injuries. NIH awarded the grantee a Recovery Act grant of \$3 million for research related to neurological recovery from spinal cord injury and stroke. The grant budget period is April 15, 2010, through March 31, 2013. As of March 31, 2011, the grantee had claimed \$950,844 under the NIH grant.

OBJECTIVE, SCOPE AND METHODOLOGY

Objective

Our objective was to determine whether costs claimed by the grantee were allowable under the terms of the grant and applicable Federal regulations.

Scope

We reviewed the total \$950,844 in costs that the grantee claimed for the NIH grant through March 31, 2011. The grantee claimed the total amount as direct costs in support of its research project.

We limited our assessment of the grantee's internal controls to those that relate to our audit objective. We performed

fieldwork at the grantee's administrative office in New Haven, Connecticut, in July and August 2011.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and other guidance;
- reviewed grant announcements, grant applications, and grant award notices;
- identified expended funds in the grantee's accounting records as of March 31, 2011;
- summarized costs by cost category from expenditure reports;
- recalculated amounts on the March 31, 2011, expenditure report to verify mathematical accuracy;
- analyzed differences between budgeted and actual expenditures;
- reviewed costs claimed under the grant for allowability; and
- discussed the results of our review with grantee officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

FINDING AND RECOMMENDATION

The grantee claimed costs of \$950,844 that were allowable under the terms of the grant and applicable Federal regulations; however, the grantee did not account for the \$53,966 in proceeds earned from the sale of equipment that was purchased for the grant.

FEDERAL REQUIREMENTS

Pursuant to the program income rules at 45 CFR 74.24(g), proceeds from the sale of property should be handled using the rules at 45 CFR 74.30-37. Section 74.34(g)(4) states that "[i]f the recipient's project or program for which or under which the equipment was acquired is still receiving support from the same HHS program, and if the HHS awarding agency approves, the net amount due may be used for allowable costs of that project or program. Otherwise the net amount must be remitted to the HHS awarding agency by

check.” The NIH Grants Policy Statement (December 2003)¹ states that NIH applies the additive alternative to all grantees, including for-profit entities, unless the program income is earned as a result of the sale of, among other things, equipment. In that case, if the grantee is still receiving support for the grant from NIH at the time of the sale, “the grantee must credit the NIH share of the proceeds to the grant and use that amount under the deductive alternative for program income.”²

SALE OF EQUIPMENT

In July 2010, the grantee purchased a used biologics lab to conduct the research described in the grant. The grantee purchased the entire lab, including all of the equipment contained in the lab. The purchase price of the lab equipment was approximately \$317,000, whereas its value new, according to the grantee, was \$1,082,000. The lab included most of the equipment that the grantee needed to conduct the required research, but the lab also included some equipment that the grantee did not need. In December 2010, the grantee sold the equipment that it did not need for \$53,966. The grantee’s NIH grants management officer verbally authorized the grantee to use these funds in support of the grant in the future. The grantee determined that the funds from the sale of the equipment would be used to support the grant in grant year 2.

RECOMMENDATION

We recommend that NIH work with the grantee to account for the \$53,966 in proceeds earned from the sale of the equipment.

AXERION THERAPEUTICS COMMENTS

In written comments on our draft report, the grantee did not concur with our initial recommendation that NIH recover \$53,150³ that the grantee claimed for unallowable equipment costs. The grantee stated that it had an opportunity to purchase a biologics lab, which included equipment, to conduct the research outlined in the grant award. The grantee stated that it sold pieces of equipment during 2010 that it concluded were not necessary for the research grant. Based on its review of the Federal regulations and

¹ This version of the NIH Grants Policy Statement was effective for all NIH grants and cooperative agreements with budget periods beginning on or after December 1, 2003, through September 30, 2010.

² Section 3.03.103-2.C.2 of the HHS *Awarding Agency Grants Administration Manual* (AAGAM) states that program income does not include the proceeds from the sale of nonexempt equipment. Equipment purchased by a commercial entity like Axerion is considered nonexempt. According to the AAGAM, these sales proceeds must be treated as an “applicable credit” pursuant to the cost principles. The applicable credit rules for commercial organizations are found at 48 CFR §§ 31.201-1(a) and 31.201-5 and require that “any income, rebate, allowance, or other credit relating to any allowable cost ... shall be credited to the Government either as a cost reduction or by cash refund.”

³ We determined that this equipment was valued at \$53,150.

discussions with NIH staff, the grantee stated that it concluded that the sale of this equipment did not require it to return the funds to NIH because it planned to use the funds to support its NIH grant research in the future. The grantee stated that it had determined that it would use the funds in grant year 2 by not requesting grant reimbursement from NIH once it exceeded \$2 million of expenses for grant years 1 and 2. The grantee's comments are included in their entirety as Appendix A.

OFFICE OF INSPECTOR GENERAL RESPONSE

After discussions with NIH officials, we revised our recommendation in this draft report. We originally recommended that NIH recover \$53,150 that the grantee claimed for unallowable equipment costs, but we now recommend that NIH work with the grantee to account for the \$53,966 in proceeds earned from the sale of the equipment.

NATIONAL INSTITUTES OF HEALTH COMMENTS

In written comments to our draft report, NIH concurred with our finding and recommendation. NIH's comments, excluding technical comments that we address in this report as appropriate, are included in their entirety as Appendix B.

APPENDIXES

to \$1,082 thousand that the equipment cost when purchased new in prior years by another organization. This was an “all or nothing” purchase opportunity and allowed Axerion to begin operations immediately and hire staff to work in the lab. Axerion considered many factors when considering the purchase of this equipment including:

- Significant cost savings as compared to purchasing the equipment new
- The several months it would have taken to purchase the equipment new and set up the equipment in a lab
- Axerion’s ability to create jobs quickly, an essential guideline as part of all Recovery Act awards

Axerion purchased the used lab equipment in July 2010 utilizing NIH funds.

The Vice President of Process Science conducted a detailed review of the newly purchased lab equipment in the third quarter of 2010 and concluded that a couple of pieces of equipment were not necessary. The Vice President of Process Science sold certain pieces of equipment in the third and fourth quarter of 2010.

During the first quarter of 2011, a significant amount of research was conducted to determine if the funds received from the sale of the equipment would be required to be returned to the NIH since these funds were originally purchased with NIH Grant Funds. A review of 45 CFR Part 74 “UNIFORM ADMINISTRATIVE REQUIREMENTS FOR AWARDS AND SUBAWARDS TO INSTITUTIONS OF HIGHER EDUCATION, HOSPITALS, OTHER NONPROFIT ORGANIZATIONS, AND COMMERCIAL ORGANIZATIONS” was conducted with particular attention given to 74.30 – 74.37 and 74.82. In addition to a review of these terms and conditions, a discussion was held with Jeannette Gordon, the Grants Management Officer assigned to our NIH Grant. Based on the review of 45 CFR Part 74 and discussions with Jeannette Gordon, it was concluded that the sale of this equipment would not require the return of funds to the NIH in the event that these funds would be used in support of the specific aims in the NIH Grant in the future. After a review of the planned expense of the Nogo research budget from April 1, 2011 to March 31, 2012 it was determined that these funds from the sale of equipment would be utilized by the grant in grant year 2. This would be accomplished by not requesting reimbursement for funds spent on the Nogo research once we exceeded \$2.0 million of expenses for grant year 1 and 2.

As of March 13, 2012, our actual and planned expenditures through the end of grant year 2 (March 31, 2012) are projected to be approximately \$2,055,000. As previously agreed to with the NIH we will not be requesting reimbursement for the \$53,150 related to the proceeds from the sale of equipment in the third and fourth quarter of 2010. Not requesting \$53,150 of funds from the NIH related to the grant at the end of grant year 2 has the same impact as returning the funds and is what was agreed to with the NIH during the first quarter of 2011. Additionally, a memo to Axerion’s grant file regarding our conclusions and documenting our discussions with the NIH on this matter was drafted in the first quarter of 2011 and given to the Officer of Inspector General as part of their review of expenses. A copy of this memo is included as appendix 1 for further reference.

APPENDIX B: NATIONAL INSTITUTES OF HEALTH COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

TO: Michael J. Armstrong
Regional Inspector General for Audit Services, Region I, HHS

FROM: Director, NIH

SUBJECT: NIH Response to Draft Office of Inspector General Report, *Axerion Therapeutics Claimed Allowable Recovery Act Grant Costs but Did Not Account for Earned Program Income* (A-01-11-02509)

Attached are general and technical comments from the National Institutes of Health in response to the draft Office of Inspector General report entitled, *Axerion Therapeutics Claimed Allowable Recovery Act Grant Costs by Did Not Account for Earned Program Income* (A-01-11-02509).

We appreciate the opportunity to review and comment on the draft report. Should you have questions or concerns regarding our comments, please contact Meredith Stein in the Office of Management Assessment at 301-402-8482.

For 
Francis S. Collins, M.D., Ph.D.

Attachments

GENERAL COMMENTS OF THE NATIONAL INSTITUTES OF HEALTH ON THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORT ENTITLED, AXERION THERAPEUTICS CLAIMED ALLOWABLE RECOVERY ACT GRANT COSTS BUT DID NOT ACCOUNT FOR EARNED PROGRAM INCOME (A-01-11-02509)

The National Institutes of Health (NIH) appreciates the review conducted by the OIG and the opportunity to provide clarifications on this draft report. We respectfully submit the following general comments. Technical comments are included as a separate attachment.

OIG Finding 1: The grantee claimed costs of \$950,844 that were allowable under the terms of the grant and applicable Federal regulations; however, the grantee did not account for \$53,966 in program income earned from the sale of equipment that was purchased for the grant (page 2).

The NIH concurs with the finding and intends to recover \$53,966 in costs from the sale of equipment that was originally purchased as part of a used biologics lab under Recovery Act grant number 1 RC3 NS 070629-01. However, NIH does not agree that the costs be considered earnings from program income. As confirmed by the grantee, the equipment that generated income by its sale was not needed for purposes of the grant; therefore, the costs were not allocable to the grant and are unallowable. Upon further consideration, the NIH grants management officer, referenced on page 3 of the OIG report, and the Chief Grants Management Officer at the Institute, as well as NIH's Office of Extramural Research, agree that the costs of the equipment that did not benefit the project are considered unallowable, although the purchase of the biologics lab with equipment is allowable. Therefore, these costs should be regarded as unallowable costs instead of program income and should be recovered from the grantee by NIH. The NIH intends to recover the costs.