

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF NATIONAL INSTITUTES OF
HEALTH GRANTS AT ADVANCED CELL
TECHNOLOGY, INC**



**JANET REHNQUIST
INSPECTOR GENERAL
APRIL 2002
A-01-02-01500**



Office of Audit Services
Region I
John F. Kennedy Federal Building
Room 2425
Boston, MA 02203
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APR 26 2002

CIN: A-01-02-01500

Michael West, Ph.D.
President and CEO
Advanced Cell Technology, Inc.
One Innovation Drive
Worcester, MA 01605

Dear Dr. West:

The purpose of this letter is to provide you with the results of our review of the National Institutes of Health's (NIH) three grant awards made to Advanced Cell Technology, Inc. (ACT). The objectives of our audit were to: (1) determine whether the costs charged to the three NIH grants were allowable; and (2) ensure the funds were not expended, either directly or indirectly, in support of human cloning activities under the terms of the grants and applicable Federal regulations.

Based upon our review, we believe that \$149,917 of the \$214,146 in direct costs claimed to date for the three NIH grant awards are unallowable costs. Specifically, we are questioning equipment costs totaling \$114,417 charged to two ongoing grants and salary expenditures of \$35,500 charged to a completed grant. Additionally, we found no evidence that NIH funds supported ACT's human embryo cloning activities.

We noted that ACT's independent public accountants questioned ACT's ability to continue as a going concern considering its cash and working capital positions. We also have concerns regarding ACT's financial viability and the impact this would have on the continuity of research under the ongoing grants. We have additional concerns regarding the continuity of NIH-funded research considering the stated intent of its Principal Investigators (PI) to leave ACT shortly.

We recommend that ACT refund the grant awards \$149,917 of the \$214,146 in costs claimed as of March 15, 2002. We also recommend that ACT refrain from charging the NIH-funded grant awards additional costs until ACT is able to: (1) fully implement effective accounting policies and procedures; (2) provide evidence of a long term financing commitment demonstrating its ability to continue as a going concern; and (3) ensure the continuity of the NIH-funded research.

INTRODUCTION

BACKGROUND

The ACT is a commercial biotechnology corporation located in Worcester, Massachusetts. On November 26, 2001, researchers at ACT reported the cloning of a human embryo using somatic cell nuclear transfer. The Department of Health and Human Services (HHS) appropriation language prohibits the Department's funding from being used for: (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero. The Secretary of HHS has requested the Inspector General to determine whether any Federal grant funds have been used to support ACT's human embryo cloning research.

ACT has received the following three grant awards from HHS through the NIH:

- A completed small business innovation research grant (SBIR) for the "Creation of Cloned Cattle Lacking the Prion Gene" totaling \$99,729 in direct costs for the period August 1, 1999, through January 31, 2001. The NIH grant number is R43 NS38382-01.
- An ongoing grant for "Defining Critical Parameters of Mouse Cloning" for \$1,556,748 in total costs; \$967,503 in direct costs and \$589,245 in indirect costs for the period September 2001 through August 2006. The NIH grant number is R01 HD42320-01 (R01).
- An ongoing grant for "Enhanced Gene Targeting in Mammals" for \$267,000 in total costs; \$150,000 in direct costs and \$117,000 in indirect costs for the period September 2001 through August 2003. The NIH grant number is R21 GM65194-01 (R21).

Both of the ongoing grants were restricted in the use of funds awarded for indirect costs. That is, ACT could not draw down awarded indirect costs in excess of 10% for fringe benefits associated with salaries and wages until ACT received an approved indirect cost rate. As of March 15, 2002, ACT had not submitted its indirect cost rate proposal to NIH for approval. ACT has not claimed any indirect costs on either open grant award and indirect costs were not budgeted on the SBIR.

OBJECTIVES, SCOPE AND METHODOLOGY

Our review was conducted in accordance with generally accepted government auditing standards. The objectives of our audit were to: (1) determine whether the costs charged to the three NIH grants were allowable; and (2) ensure the funds were not expended, either directly or indirectly, in support of human cloning activities under the terms of the grants and applicable Federal regulations.

To accomplish these objectives, we:

- Reviewed the three NIH grant applications and award documents to obtain an understanding of the nature of the grants and the types of costs involved.
- Reviewed applicable regulations including the Code of Federal Regulations and the Public Health Service (PHS) and NIH Grants Policy Statements.
- Conducted a walkthrough of the ACT facility in Worcester to determine if the NIH funded research areas were isolated from the human cloning research areas.
- Reviewed expenditures from the NIH grants to ensure they were adequately supported in accordance with Federal regulations.
- Reviewed ACT's financial management system, including the policies and procedures manual, to determine whether it met Federal requirements for safeguarding assets and ensuring costs were assigned to projects commensurate with benefits received.
- Interviewed the PIs on the two ongoing NIH grants and reviewed their documentation to determine whether research was actively being performed.

We did not rely on the internal control structure at ACT because written policies and procedures were not in place and ACT had neither a formal nor informal system for charging salaries to projects in proportion to the benefits received. We performed our fieldwork at ACT in Worcester, Massachusetts from January 2002 through February 2002. Our draft report was issued to ACT on March 18, 2002. The ACT's written comments are summarized on pages six and seven and appended in their entirety to the report (See Appendix).

FINDINGS AND RECOMMENDATIONS

Based upon our review, we found that \$149,917 of the \$214,146 in direct costs claimed to date for the three NIH grant awards are unallowable costs. Additionally, we found no evidence that NIH funds supported ACT's human embryo cloning activities.

We noted that ACT's independent public accountants questioned ACT's ability to continue as a going concern considering its cash and working capital positions. We also have concerns regarding ACT's financial viability and the impact this would have on the continuity of research under the ongoing grants. We have additional concerns regarding the continuity of NIH-funded research considering the stated intent of its PIs to leave ACT shortly. We discuss these areas in more detail below.

UNALLOWABLE COSTS

SBIR Grant

ACT charged direct costs of \$99,729 to the completed SBIR grant. Through our testing of invoices and other support, we were able to obtain reasonable assurance that the non-salary expenditures totaling \$64,229 were allowable costs. However, we were unable to verify that the salaries charged to the grant were attributable to the grant because ACT does not utilize an effort reporting (i.e., workload distribution) system as required by Federal regulations and the PHS and NIH Grants Policy Statements. As a result, we believe that the \$35,500 in salary expenditures charged to the SBIR grant by ACT are unallowable costs.

R01 and R21 Grants

As of March 15, 2002, ACT had charged \$114,417 in equipment expenditures to the two ongoing grants. Yet, the grants' applications and awards showed \$0 in budgeted expenditures for equipment with nearly 100% of direct costs going to salary with each grant requiring full time research associates in addition to the PIs' efforts. ACT stated that NIH approved the use of grant funds to pay for the equipment because the grants were considered "modular" grants.

Our review showed that the equipment costs charged to the grants appeared to be questionable. In this regard, the equipment was on loan to the PIs in 1999 who, at the time, were working at Rockefeller University in New York. The PIs, before coming to ACT, used the loaned equipment to conduct research at Rockefeller University. The distributor loaned the equipment for a period of 15 months allowing the PIs time to obtain a grant to fund the equipment. Subsequently, ACT paid the distributor \$114,417 in January 2002 for the equipment. Our review of the equipment transaction also disclosed that:

- the use of grant funds to purchase equipment described in one of ACT's grant applications as "already available for this project" and the fact that ACT did not staff the projects in accordance with the terms of the grant awards significantly reduces the scope of research possible;
- ACT has not conducted any research under the grant to which \$35,000 in equipment was charged and we were unable to determine the extent of research conducted on the second grant because ACT does not have a system in place to distribute salaries in proportion to the benefits received; and
- the PIs stated intent to leave ACT for positions overseas by April 30, 2002, casts significant doubt as to the reasonableness of continuing to fund these grants.

Subsequently, we contacted each of the awarding Institutes and informed them of the information stated above. Upon learning of this information, officials at the Institute responsible for the R21 grant said they would not have approved the equipment expenditure. Officials at the Institute awarding the R01 grant expressed concern at the waste of a year of research funding and would make a decision about disallowing the transaction upon reviewing our report. As a result, we are questioning the allowability of \$114,417 in equipment expenditures.

SEPARATION OF FEDERAL FUNDS FROM HUMAN CLONING ACTIVITIES

Although the PI on the SBIR grant donated a cell to be used for the cloning of a human embryo, we found no evidence that NIH funds supported ACT's human cloning activities. This PI is also ACT's Director of Research and has access to all ACT laboratories. However, since no indirect costs were charged to the NIH grants, none of his activity in his capacity as Director of Research was allocated to the grants. We also verified that the laboratories for Federally sponsored research projects are physically separated from the laboratory used for human cloning activities.

ADVANCED CELL TECHNOLOGY'S ABILITY TO CONTINUE AS A GOING CONCERN

In its audit report on ACT's financial statements for the two years ended December 31, 2000, ACT's independent public accountants questioned ACT's ability to continue as a going concern considering ACT's cash and working capital positions. At our entrance conference in January, ACT's Chief Financial Officer (CFO) said bridge loans had been arranged for the short term. In addition, he assured us long term financing was available. Later in February, the CFO allowed us to review a term sheet providing for long term financing available upon ACT's acceptance by signing. However, as of the date of this report, we had not been provided a signed copy of these terms indicating the necessary financing has been put in place. As a result, we have continuing reservations regarding ACT's ability to continue as a going concern and the impact this would have on the continuity of research under the ongoing grants.

RECOMMENDATIONS

We recommend that ACT refund the grant awards \$149,917; \$114,417 for equipment charged to the R-01 and R-21 grants, and \$35,500 for salaries charged to the SBIR grant. We also recommend that ACT refrain from charging the NIH-funded grant awards additional costs until ACT is able to:

- fully implement effective accounting policies and procedures for all areas, including an adequate system for the distribution of salaries;

- provide evidence of a long term financing commitment demonstrating its ability to continue as a going concern and protect the government's interests; and
- ensure the continuity of the Federally funded research considering the decision of the PIs to leave ACT shortly.

AUDITEE COMMENTS

In its response to our March 18, 2002 draft report, ACT did not disagree with the validity of the facts presented in the report. However, ACT did not address our recommendations to: (1) refund the grant awards \$149,917; \$114,417 for equipment charged to the R-01 and R-21 grants and \$35,500 charged to the SBIR grant; and (2) refrain from charging the NIH-funded grants awards until specific conditions outlined in the recommendations section of our report were met. Below, we have included ACT's relevant comments and additional OIG comments. The full text of ACT's comments are included as an APPENDIX to this report.

SBIR Grant

Auditee Comments

In its response, ACT acknowledged it could not identify the exact hours worked on the SBIR grant because of the absence of an effort reporting system. However, ACT maintains that since the grant was completed and findings reported, it is clear time was spent on performing the activity under the grant.

Additional OIG Comments

Since ACT did not have an effort reporting system in place to account for the distribution of salaries, it was unable to provide support for personnel that actually worked on the SBIR grant and the number of hours charged to the grant by personnel. Therefore, we believe that the \$35,500 in salary expenditures charged to the SBIR grant by ACT are unallowable costs.

R01 and R21 Grants

Auditee Comments

In its response to our audit of the two ongoing grants, ACT requests we clearly state there has been no misappropriation of funds associated with the equipment purchase. ACT states that the NIH grant officer approved the use of grant funds for the equipment purchase. ACT maintains that although NIH may have erred in approving the equipment purchase, ACT acted in accordance with NIH's instructions. As to the continuity of the research, ACT acknowledges the PIs are leaving ACT for positions overseas. As a result, ACT will abandon the R-21 grant. However, ACT intends to name a new PI for the R-01 grant and it will submit the PI's name to NIH for approval shortly.

Additional OIG Comments

Our report does not state, nor do we imply, that ACT misappropriated grant funds to purchase the equipment. However, we did question the allowability of the equipment costs charged to the grants based upon the facts surrounding the equipment purchase as detailed in our report. Upon review of the additional information we provided, the officials responsible for the R-21 grant stated they would not have approved the use of grant funds for the equipment purchase had they known the details of the transaction. We continue to recommend that ACT refund the grant awards \$149,917 for equipment charged to the respective grants.

Although ACT has decided to abandon the R-21 grant, the continuity of Federally funded research on the R-01 grant is still in question due to the issues stated in our report. Therefore, we continue to recommend that ACT refrain from charging this grant award until NIH approves appointment of a new PI and ACT establishes effective accounting procedures and provides evidence of its ability to continue as a going concern.

Advanced Cell Technology's Ability to Continue as a Going Concern

Auditee Comments

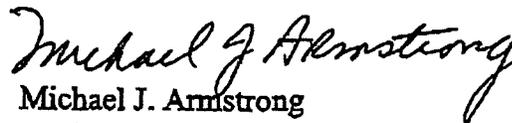
The ACT takes issue with our reporting on ACT's viability as a going concern. ACT states that its independent auditors raised the going concern issue in the 2000 audit and ACT has since operated for over one year, indicating the statement in the auditors' report was cautionary. ACT further states that as a private company it has neither the obligation nor desire to publicly disclose the terms of financing discussed with its private investors and will not provide OIG with a signed termsheet. ACT believes the "going concern" reference in the report is not applicable and is potentially damaging to the Company because OIG reports are public documents. Thus, ACT requests the "going concern" reference that originated in the independent auditors' 2000 financial statement report be removed from our report.

Additional OIG Comments

Our report clearly states the question of ACT's financial viability was raised in ACT's independent auditors' financial statement report for the two years ended December 31, 2000. During the course of our audit, ACT did not provide evidence that it had resolved the question of its financial viability.

In order to facilitate identification, please refer to Common Identification Number A-01-02-01500 in all correspondence relating to this report.

Sincerely yours,

A handwritten signature in cursive script that reads "Michael J. Armstrong". The signature is written in black ink and is positioned above the printed name.

Michael J. Armstrong
Regional Inspector General
for Audit Services

APPENDIX



ADVANCED CELL TECHNOLOGY

April 17, 2002

U.S. Department of Health and Human Services
Room 2425
John F. Kennedy Federal Building
Boston, MA 02203

Attention: Richard A. Navarro, CPA

RE: Common I.D. Number A-01-02-01500

Dear Mr. Navarro:

First, regarding your comments about our prior *SBIR Grant*. As you have pointed out, ACT did not have an effort reporting system at the time of this grant, and consequently we agree that the Company cannot identify the exact hours worked on this grant. We would like to emphasize, however, since the grant was completed and findings reported, it is clear that the time was spent on performing the activity under the grant.

Second, regarding the *R01 and R21 Grants*. We request that the report would state more clearly that there has been no misappropriation of funds associated with this equipment purchase. When requested by the PI, NIH explicitly approved the use of funds to purchase this equipment. Prior to drawing the funds, the Company's Accounting Manager subsequently confirmed the NIH approval directly with the grant officer at NIH, who confirmed that this expenditure was indeed allowed under the grants. It is possible that NIH made a mistake when it approved this purchase, but the Company acted in accordance with the instructions it received from NIH.

The PIs of these grants are leaving ACT, and will soon relocate to the Riken Center for Developmental Biology in Kobe, Japan.

- ACT will not assign a new PI to the grant entitled "Enhanced Gene Targeting in Mammals." This grant will be abandoned.
- ACT has not yet made the decision as to the named PI for the grant entitled "Defining Critical Parameters of Mouse Cloning." We will submit that name for approval shortly.

Third, regarding the "going concern" mentioned in the 2000 audit. We would like to clarify that ACT is a privately held company, funded by private sources. As many biotechnology companies, we raise funds periodically to meet our financing needs. At the time of the 2000 audit the Company's cash position was such that our independent auditors issued a going concern in their audited report. The Company has since operated for over one year, which would indicate the statement in the auditors' report was on the cautionary side. As a private company ACT has neither an obligation nor a desire to

publicly disclose the terms discussed with potential investors in the company and can therefore not provide OIG with a copy of a signed termsheet. We believe this reference in your report is inapplicable and potentially damaging to the Company if put in the public domain. We would respectfully request that reference to the "going concern" in the 2000 audit be removed from your report. Copies of current termsheets are available for review by a designated OIG representative under confidentiality.

Sincerely,

A handwritten signature in black ink, appearing to read 'Michael D. West', with a large, stylized flourish at the end.

Michael D. West, Ph.D.
President and Chief Executive Officer

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