

Internal Audit Report

Grantee: Caliber Biotherapeutics

Report #2013-09

August 29, 2013



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Introduction

As part of the Cancer Prevention Research Institute of Texas (“CPRIT”) FY 2013 Grantee Internal Audit plan, a review of Caliber Biotherapeutics, LLC has been completed.

Background

Caliber Biotherapeutics, LLC (“Caliber”) is a biotechnology company based in Bryan, Texas with a mission to develop and commercialize protein-based therapeutics that improve outcomes for patients with cancer and other diseases. Caliber utilizes technological innovations in biological research, product development and manufacturing to create treatments with increased safety and effectiveness--while reducing both costs and development time. Caliber operates the world’s largest *N. benthamiana* expression based protein manufacturing facility in College Station, Texas. Caliber’s technologies are being supported by the Cancer Prevention and Research Institution of Texas (CPRIT), DARPA and several Texas based life sciences investors.

CPRIT awarded Caliber a three year, \$12.8 million grant¹ at the end of 2011 to help develop a portfolio of monoclonal antibodies (mABs) that are based upon leading cancer therapeutics. Using its globally recognized plant-based production system initially developed by the federal government for US biosecurity, Caliber will develop Rituxan biobetters that have enhanced cytotoxicity against cancer cells, while imposing no additional safety risks to patients.

Audit Objectives and Scope

Objectives

1. To determine if expenditures were appropriate, adequately documented, and in compliance with CPRIT’s policies.
2. To evaluate the effectiveness and timeliness of current administrative processes related to the CPRIT grant.
3. To evaluate the internal control environment for expenses related to the CPRIT grant.
4. To determine if CPRIT award recipients have an amount of matching funds equal to one-half of the award dedicated to the research that is the subject of the grant request.
5. To determine if CPRIT award recipients are utilizing matching funds towards the same area of cancer research that is the subject of the award.
6. To determine if equipment was approved appropriately prior to acquisition, adequately documented, and in compliance with CPRIT’s policies.
7. To observe and verify existence of acquired equipment.

Scope

1. Caliber’s expenses, inventory, and matching funds related to the CPRIT grant, between September 2011 and May 2013, were covered under the scope of this audit.
2. Detailed testing of selected expense transactions was performed.
3. Selected equipment over \$5,000 was observed on-site.
4. Detailed testing of selected matching fund expenditures was performed.

¹ Figures provided by the CPRIT website. <http://www.cprit.state.tx.us/funded-grants/>

Summary of Findings

Internal Audit noted the following findings during the review of Caliber:

- Caliber inconsistently categorizes expenses between CPRIT's categories such as 'contractual,' 'supplies,' and 'other.'
- Caliber incorrectly claimed taxes totaling approximately \$6,500 on the financial status reports (FSR) for the period 12/1/2011 – 5/31/2012.

The inconsistencies noted above display deficiencies within Caliber's understanding of CPRIT's allowable and unallowable costs and matching funds process.

Testing Approach

Expense Reimbursements

Analytical and substantive procedures for Caliber's expenses, inventory, and matching funds related to the selected CPRIT grant was performed to ensure the grantee complied with CPRIT policy. Through interviews with appropriate personnel, detailed testing of expenditures, observation of equipment, and analysis of the matching funds process, Internal Audit developed an understanding of the key processes and activities related to the CPRIT grant expense reimbursement, inventory, and matching funds process.

Our procedures included discussions with the following Caliber personnel:

Name	Title
Evelyn Chu	Staff Accountant
Lisa Cox	Accounting Manager

Substantive testing was applied subjectively to selected CPRIT expense transactions. These transactions were selected from financially material categories (such as payroll, fringe benefits, travel, equipment, supplies, contractual, and other) comprising approximately 75% of expenditures within the CPRIT FSR. One to five expenditures were sampled for each material category and supporting documents were reviewed for accuracy, completeness, appropriateness, classification and timing. Examples of supporting documents include invoices, receipts, and employee expense reports. Internal Audit also verified that each sampled expense was allowable per CPRIT's Expense Reimbursement Policy.

Inventory & Equipment

Internal Audit obtained a complete listing of inventory from the Consolidated Grants Management System (CGMS) for the selected grant, and noted that there were no inventory items reported.

Matching Funds

Detailed testing of matching funds was performed to ensure that Caliber matched the required 50% of CPRIT funds (on an annual basis). From matching funds, expenditures were selected and tested to ensure that the corresponding expenditure was related to cancer research. Documentation was obtained for each of the selected expenditures to support the appropriateness of the fund being used as a match.

Audit Results

Expense Reimbursements

During the walkthrough of current procedures, Internal Audit noted that staff had some difficulties allocating expenses due to system limitations of Great Plains. This could result in additional inconsistencies in the cost allocation process. The time and effort allocation of expenses appeared to take a lot of time and effort and seemed inefficient.

Internal Audit also noted that Caliber inconsistently categorized expenses between the “contractual,” “other,” and “supplies” line items. For the period of December 1, 2012 – May 31, 2013, from the items sampled, the misclassification totaled approximately \$2,900. Expenses classified as “contractual” in prior periods, but in more recent periods, these expenses were classified as “other.” Supply expenses that were previously classified correctly were now being classified as “other.” The inconsistent classification of expenses runs the risk of allowing expenses that were not previously budgeted for on the grantee application.

Recommendations

Caliber exhibited some understanding and effective processes related to expense reimbursements and the matching funds requirement. However, there are some areas that need to be improved upon to ensure Caliber fully understands CPRIT’s policy. Right before the Caliber grantee visit, a key individual heavily involved with the CPRIT reimbursement process left the company. The new individual was still learning about the grant reimbursement process during the review. Caliber should ensure that procedures are properly documented to ensure the most current process is reflected to avoid any potential knowledge gaps. In the absence of the employee who has the responsibility, Caliber should make sure that someone else has the ability to quickly fill in. The documentation would also cut down on the inconsistent treatment of expenses on the FSR from period to period.

CPRIT Management Action Plan

CPRIT Finance has followed up with the grantee to address these issues by:

1. Requiring the grantee to reclassify all project costs of past financial reporting periods during fiscal year 2012 from December 1, 2011 through August 31, 2012; and
2. Requiring the grantee to issue a credit in the amount of the unallowable project costs for taxes totaling \$6,500 on the next financial report to CPRIT and to review all project costs in financial reports from 6/1/2012 through 5/31/2013 to verify that there are no additional tax payments claimed in those reports that should be credited to the grant.