

Internal Audit Report

Grantee: Molecular Templates

Report #2014-103

July 11, 2014



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Introduction

As part of the Cancer Prevention Research Institute of Texas (“CPRIT”) FY 2014 Grantee Internal Audit plan, a review of Molecular Templates Inc. has been completed.

Background

Molecular Templates (MTEM) is a privately held, biopharmaceutical company based in Texas that aims to develop novel targeted biologic cancer therapeutics called Engineered Toxin Bodies that will have a clinically meaningful impact on patient outcomes for areas of high unmet medical need. MTEM was set up in 2009 and operates its own 4,000 sq. ft. wet-lab space at the Texas Life Sciences Collaboration Center where the company currently employs seventeen full-time and two part-time employees. Four employees with PhD degrees in biotechnology and three with MBAs were recruited to Texas specifically to work with Molecular Templates.

Since CPRIT’s establishment in 2008, Molecular Templates has been awarded one product development grant (CC121020) totaling \$10,600,000¹. This CPRIT grant provides funds to advance research on MT-3724, its lead drug, by:

- Completing the required studies and manufacturing that enable an investigational new drug application (IND) for MT-3724 to be submitted to the FDA.
- Conducting a phase I trial in patients with non-Hodgkin’s lymphoma (NHL) to determine safety, pharmacokinetics, and the recommended phase II dose (RP2D) for MT-3724.
- Demonstrating efficacy of MT-3724 in a phase II study in NHL cancer patients that can lead to a pivotal phase 3 trial.

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.

Scope

1. Molecular Template’s expenses and matching funds related to the CPRIT grant identified above, between September 2012 and May 2014 were covered under the scope of this audit.
2. Detailed testing of selected expense transactions was performed.
3. Detailed testing of matching fund expenditures was performed.

Note: This audited grant did not receive funds to purchase equipment so this area was not in scope.

Summary of Findings

Internal audit did not note any significant findings or exceptions during the audit of Molecular Templates.

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

Testing Approach

Analytical and substantive procedures for Molecular Template's expenses and matching funds related to the CPRIT grant were performed to ensure the grantee complied with CPRIT policy. Through interviews with appropriate personnel, detailed testing of expenditures 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 and matching funds process.

Our procedures included discussions with the following Molecular Templates personnel:

Name	Title
Jason Kim	Chief Financial Officer
Deborah May	Director of Finance and Administration

Substantive testing was performed on subjectively selected transactions. These transactions were selected from financially material categories (including supplies, contractual, and other) comprising approximately 80% of expenditures within the CPRIT Financial Status Report (FSR) submitted during the period. For each sample selected, supporting documents were reviewed for accuracy, completeness, appropriateness, classification and timing. Supporting documents consisted of invoices from suppliers. Internal Audit also verified that each sampled expense was allowable per CPRIT's Expense Reimbursement Policy.

Detailed testing of matching funds was performed to ensure that the required 50% match to CPRIT funds was achieved. Documentation was obtained and reviewed for selected expenditures to support the appropriateness of the monies being used as match and to ensure that the expenditure was related to advance Molecular Template's lead drug, MT-3724.

Audit Results

Expense Reimbursements

Interviews with key personnel regarding the expense reimbursement process were conducted to ensure that appropriate controls were in place to comply with CPRIT policies and procedures. To evaluate the effectiveness of Molecular Template's expense reimbursement process, Internal Audit performed substantive testing on 227 expense reimbursement transactions totaling over \$2.5 million during the period of September 2012 – May 2014 for the grants selected as part of the review. Internal Audit vouched the expenses per the general ledger to the supporting documents.

Internal Audit then traced the transactions within the general ledger to the Form 269A to ensure that all amounts were accurately reported and that expenses were appropriately categorized and reported to CPRIT. Internal Audit also determined that all expenses were incurred within the dates set forth in the CPRIT grant contract and that no expense was reimbursed prior to it being incurred by the grantee. Upon review of all requested documentation, it was noted that appropriate supporting documentation was available for all samples selected and all expenses claimed were allowable.

Matching Funds

To support Molecular Template's matching funds certification claimed in attachment C of the CPRIT contract, Internal Audit obtained evidence of income used to meet the matching funds requirement. The income originated from funds independent of CPRIT and was used within the same research area as the CPRIT grant selected for testing. Molecular Templates provided sufficient and appropriate evidence to support the income which made up the matching funds amount. From conversations with the Chief Financial Officer and the Director of Finance and Administration, it was validated that the matching funds were also provided to advance Molecular Template's lead drug, MT-3724. Internal Audit concluded that the funds being used for the CPRIT required match are appropriate and meet the requirements described in CPRIT policies and procedures.