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June 2, 1999

Mr. Dennis Whalen
Executive Deputy Commissioner
Department of Health
Tower Building, Room 1408
Empire State Plaza
Albany, New York 12237

Re: Report 99-F-9

Dear Mr. Whalen:

Pursuant to the State Comptroller's authority as set forth in Article V, Section 1 of the State Constitution and Article II, Section 8 of the State Finance Law, we have reviewed the actions taken by officials of Health Research, Incorporated (HRI) as of May 5, 1999, to implement the recommendations contained in our audit report, *Health Research, Inc.* (Report 97-S-11). Our report, which was issued on May 22, 1997, examined HRI's administration of the agreement with the Institut Merieux and the Virogenetics Corporation to develop and market the pox-virus vaccinia, which was licenced to them.

Background

HRI was established in 1953 as a not-for-profit corporation, by administrative action of the Commissioner of the Department of Health (Department) who is also President of HRI. HRI's primary purpose is to administer Federal, State and private funding to support, supplement and extend the research functions and programs of the Department. Gifts and donations made to HRI are tax-exempt. During the 1997-98 State fiscal year HRI received about \$210.4 million from grants, contracts and donations, and earned \$6.6 million from technology transfer revenues, investment interest and contract fees. HRI employs over 1,400 administrative and technical support staff.

Most of HRI's major research projects are carried out in State facilities, using State scientists and available administrative and laboratory resources. HRI employees often work side-by-side with Department employees and generally share similar job responsibilities. HRI maintains its executive office in Rensselaer, New York, and operates divisions in Albany and Buffalo. The Albany Division works in cooperation with the Wadsworth Center for Laboratories and Research, which is the

Department's research arm. The Buffalo Division works in cooperation with Roswell Park Cancer Institute, which is primarily a cancer research hospital that is affiliated with the Department.

The Department contracts with HRI. The major provisions of the contract are:

- the Department is responsible for the overall supervision and direction of HRI activities;
- HRI pays the State monthly for a portion of the State's indirect costs (personal service, facilities and support services provided by the Department); and
- the State authorizes HRI to serve as the technology transfer and copyright administrator for the Department.

This contract is generally renewed every two years and is submitted to the Attorney General and the State Comptroller for approval. However, the most currently approved contract covers the two year period ended March 31, 1995.

In 1986, HRI entered into a joint venture agreement (agreement) with the Institut Merieux (Merieux), a private corporation, based in France, creating the Virogenetics Corporation (Virogenetics), which is located in Rensselaer, New York. The purpose of Virogenetics is to develop the pox-virus vaccinia technology which was invented by a Department employee.

Under the terms of the agreement, HRI provided Virogenetics with exclusive, royalty free rights to the technology in return for 49 percent of Virogenetics stock. The agreement provided Merieux an option to increase its 51 percent share in Virogenetics to 80 percent by purchasing shares from HRI, which Merieux exercised in December 1990.

The agreement further provided Merieux with the option of purchasing the remaining 20 percent share of Virogenetics held by HRI, at a fair market value negotiated between HRI and Merieux during the period March 31, 1995 through March 30, 1996. The agreement also provided HRI the option of requiring Merieux to purchase the remaining shares. In May 1996, the Office of the State Comptroller approved an extension of these contract terms, which was formally executed in June 1996. The new fair market valuation period began August 31, 1997 and extended through September 30, 1998. The buy-out option period began September 30, 1998 and extended though March 31, 1999, or 30 days following the final decision of an arbitration hearing.

Summary Conclusions

In our prior audit, we found that HRI was not adequately monitoring the terms of its agreement with Merieux regarding Virogenetics' progress in developing and marketing the pox-virus vaccinia, which was licensed to them. As a result, neither the Department nor HRI could be adequately assured that the State's interest would be protected during the fair market valuation period and subsequent buy-out option period.

In our follow-up review, we found that HRI officials have made progress in implementing the two recommendations contained in our prior audit report. HRI officials have taken steps to protect the State's interest in the transfer of the pox-virus vaccinia technology. HRI has retained the services of a major accounting firm, which has demonstrated experience in the biotechnology field, for the purpose of determining the fair market value of Virogenetics. Both HRI and Merieux obtained independent valuations of Virogenetics, which differed by as much as \$80 million. The two parties were not able to reach agreement on a sale price and, consequently, as of May 5, 1999, HRI and Merieux were in the process of entering arbitration hearings in which a valuation will be determined and adhered to by both parties.

Summary of Status of Prior Audit Recommendations

Of the two prior audit recommendations, HRI officials have implemented one recommendation and partially implemented one recommendation.

Follow-up Observations

Recommendation 1

During the period leading up to August 31, 1997 and to protect the State's interest, HRI and the Department should ensure that all terms of the agreement are complied with and that all appropriate steps to establish Virogenetics' fair market value are taken.

Status - Partially Implemented

Agency Action - HRI officials have taken steps to protect the State's interests in the transfer of the pox-virus vaccinia technology. HRI instituted a formal request for proposal process seeking qualified bidders to determine the fair market value of its 20 percent interest in Virogenetics. Bids were received from four companies and HRI completed its evaluation of these firms in September 1997. HRI awarded the contract to a major accounting firm which had demonstrated experience in the biotechnology field. Merieux also awarded a contract for similar services to another accounting firm. HRI also receives monthly reports from Merieux as part of its monitoring efforts of Virogenetics' activities. These reports include information on Virogenetics' research activities as well as unaudited financial statements.

However, we note that the agreement with Merieux stated that HRI should receive annual certified financial statements from Virogenetics. As of March 1999, HRI had not received certified financial statements for the periods ended December 31, 1997 or December 31, 1998. The unaudited financial statements that HRI receives contains only basic information without description of the accounts and they do not contain any of the notes to the financial statements. As reported in the prior audit, HRI needed to review more descriptive information to determine whether Merieux and Virogenetics did their best to sell developed

products. HRI officials contend that certified statements would not be of much benefit to them because sale of pox-virus vaccinia technology has been minimal to date.

Recommendation 2

To protect the State's interest, the Department should review any proposed agreement with an independent investment banker.

Status - Implemented

Agency Action - As stated in the Agency Action section for recommendation 1, HRI retained the services of a major accounting firm to establish the fair market value of its interest in Virogenetics. The valuation is complete and a draft copy of the report was made available to us. Merieux also obtained an independent valuation. HRI and Merieux exchanged valuation figures in April 1998. The two valuations differ substantially (by as much as \$80 million). Despite their attempts to resolve this difference, HRI and Merieux were unable to reach agreement on a sale price. Consequently, on February 9, 1999, HRI and Merieux agreed to have this dispute settled by an independent arbitrator who will establish a valuation that will be binding on all parties. According to HRI officials, hearings to resolve this matter are expected to occur during the summer of 1999.

Major contributors to this report were Ed Durocher and Ken Cox.

We would appreciate your written response to this report within 30 days, indicating any additional actions planned or taken to address any unresolved matters discussed in this report. We also thank the management and staff of the Department of Health and Health Research, Incorporated for the courtesies and cooperation extended to our auditors during this review.

Very truly yours,

Kevin M. McClune
Audit Director

cc: Mr. Charles Conaway