

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of  
The Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported) **September 22, 2014**

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**Tekmira Pharmaceuticals Corporation**

(Exact name of registrant as specified in its charter)

**British Columbia, Canada**  
(State or other jurisdiction  
of incorporation)

**001-34949**  
(Commission File Number)

**980597776**  
(IRS Employer Identification No.)

**100-8900 Glenlyon Parkway  
Burnaby, British Columbia  
Canada**  
(Address of principal executive offices)

**V5J 5J8**  
(Zip Code)

Registrant's telephone number, including area code: **(604) 419-3200**

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(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 8.01. Other Events.**

On September 22, 2014 the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

Exhibit 99.1. Press release dated September 22, 2014

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## SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**Tekmira Pharmaceuticals Corporation**

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(Registrant)

/s/ **BRUCE G. COUSINS**

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**September 22, 2014**

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(Date)

Bruce G. Cousins

*Executive Vice President and Chief Financial Officer*

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**Exhibit Index**

99.1 Press release dated September 22, 2014

## Tekmira Establishes Regulatory Framework for Emergency Use of TKM-Ebola

VANCOUVER, British Columbia, Sept. 22, 2014 (GLOBE NEWSWIRE) -- Tekmira Pharmaceuticals Corporation (Nasdaq:TKMR) (TSX:TKM), a leading developer of RNA interference (RNAi) therapeutics, today announced that the FDA has authorized Tekmira to provide TKM-Ebola for treatment under expanded access protocols to subjects with confirmed or suspected Ebola virus infections.

"Tekmira is reporting that an appropriate regulatory and clinical framework is now in place to allow the use of TKM-Ebola in patients. We have worked with the FDA and Health Canada to establish this framework and a treatment protocol allowing us to do what we can to help these patients," said Dr. Mark J. Murray Tekmira's President and CEO.

"We have insisted on acting responsibly in the interest of patients and our stakeholders," added Dr. Murray. "Today we are reporting that, working closely with regulators in the United States and Canada, we have established a framework for TKM-Ebola use in multiple patients. In the US, the FDA has granted expanded access use of TKM-Ebola under our Investigational New Drug application (IND) and Health Canada has established a similar framework, both of which allow the use of our investigational therapeutic in more patients."

"We have already responded to requests for the use of our investigational agent in several patients under emergency protocols, in an effort to help these patients, a goal we share with the FDA and Health Canada. TKM-Ebola has been administered to a number of patients and the repeat infusions have been well tolerated. However, it must be kept in mind that any uses of the product under expanded access, does not constitute controlled clinical trials. These patients may be infected with a strain of Ebola virus which has emerged subsequent to the strain that our product is directed against, and physicians treating these patients may use more than one therapeutic intervention in an effort to achieve the best outcome," said Dr. Murray. "Our TKM-Ebola drug supplies are limited, but we will continue to help where we can, as we continue to focus on the other important objectives we have to advance therapies to meet the unmet needs of patients."

TKM-Ebola is an investigational therapeutic, being developed under an FDA approved IND, which is currently the subject of a partial clinical hold under which the FDA has allowed the potential use of TKM-Ebola in individuals with a confirmed or suspected Ebola virus infection.

### About FDA Expanded Access Program

Expanded access is the use of an investigational drug outside of a clinical trial to treat a patient, with a serious or immediately life-threatening disease or condition, who has no comparable or satisfactory alternative treatment options. FDA regulations allow access to investigational drugs for treatment purposes on a case-by-case basis for an individual patient, or for intermediate-size groups of patients with similar treatment needs who otherwise do not qualify to participate in a clinical trial. (Source: [www.fda.com](http://www.fda.com))

### About TKM-Ebola, an Anti-Ebola Virus RNAi Therapeutic

TKM-Ebola, an anti-Ebola virus RNAi therapeutic, is being developed under a \$140 million contract with the U.S. Department of Defense's Medical Countermeasure Systems BioDefense Therapeutics (MCS-BDTX) Joint Product Management Office. Earlier preclinical studies were published in the medical journal *The Lancet* and demonstrated that when siRNA targeting the Ebola virus and delivered by Tekmira's LNP technology were used to treat previously infected non-human primates, the result was 100 percent protection from an otherwise lethal dose of Zaire Ebola virus (Geisbert et al., *The Lancet*, Vol. 375, May 29, 2010). In March 2014, Tekmira was granted a Fast Track designation from the U.S. Food and Drug Administration for the development of TKM-Ebola.

### About Joint Project Manager Medical Countermeasure Systems (JPM-MCS)

This work is being conducted under contract with the U.S. Department of Defense Joint Project Manager Medical Countermeasure Systems (JPM-MCS). JPM-MCS, a component of the Joint Program Executive Office for Chemical and Biological Defense, aims to provide U.S. military forces and the nation with safe, effective, and innovative medical solutions to counter chemical, biological, radiological, and nuclear threats. JPM-MCS facilitates the advanced development and acquisition of medical countermeasures and systems to enhance biodefense response capability. For more information, visit [www.jpeocbd.osd.mil](http://www.jpeocbd.osd.mil).

### About Tekmira

Tekmira Pharmaceuticals Corporation is a biopharmaceutical company focused on advancing novel RNAi therapeutics and providing its leading lipid nanoparticle (LNP) delivery technology to pharmaceutical partners. Tekmira has been working in the field of nucleic acid delivery for over a decade and has broad intellectual property covering LNPs. Further information about Tekmira can be found at [www.tekmira.com](http://www.tekmira.com). Tekmira is based in Vancouver, B.C. Canada.

### Forward-Looking Statements and Information

This news release contains "forward-looking statements" or "forward-looking information" within the meaning of applicable securities laws (collectively, "forward-looking statements"). Forward-looking statements in this news release include statements about Tekmira's strategy, future operations, clinical trials, prospects and the plans of management; an appropriate regulatory and

clinical framework for emergency use of TKM-Ebola in subjects with confirmed or suspected Ebola infections; FDA grant of expanded access use of TKM-Ebola under Tekmira's IND; Health Canada's establishment of a similar framework for TKM-Ebola; Tekmira's response to requests for the use of TKM-Ebola in several patients under emergency protocols and the results thereon; the current supply of TKM-Ebola drug; the partial clinical hold on the TKM-Ebola IND by the FDA (enabling the potential use of TKM-Ebola in individuals with a confirmed or suspected Ebola virus infection); the quantum value of the contract with the JPM-MCS; and Fast Track designation from the FDA for the development of TKM-Ebola.

With respect to the forward-looking statements contained in this news release, Tekmira has made numerous assumptions regarding, among other things, the clinical framework for emergency use of TKM-Ebola. While Tekmira considers these assumptions to be reasonable, these assumptions are inherently subject to significant business, economic, competitive, market and social uncertainties and contingencies.

Additionally, there are known and unknown risk factors which could cause Tekmira's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements contained herein. Known risk factors include, among others: TKM-Ebola may not prove to be effective in the treatment of Ebola infection under the emergency use framework, or at all; any uses of TKM-Ebola under emergency INDs are not controlled trials, and TKM-Ebola may be used on Ebola strains that have diverged from the strain to which TKM-Ebola is directed, and physicians treating patients may use more than one therapeutic intervention in addition to TKM-Ebola; the current supply of TKM-Ebola is limited, and Tekmira may not be able to respond to future requests for help in the current Ebola outbreak; the FDA may not remove the partial clinical hold on the TKM-Ebola IND; the FDA may refuse to approve Tekmira's products, or place restrictions on Tekmira's ability to commercialize its products; anticipated pre-clinical and clinical trials may be more costly or take longer to complete than anticipated, and may never be initiated or completed, or may not generate results that warrant future development of the tested drug candidate; and Tekmira may not receive the necessary regulatory approvals for the clinical development of Tekmira's products.

A more complete discussion of the risks and uncertainties facing Tekmira appears in Tekmira's Annual Report on Form 10-K and Tekmira's continuous disclosure filings, which are available at [www.sedar.com](http://www.sedar.com) or [www.sec.gov](http://www.sec.gov). All forward-looking statements herein are qualified in their entirety by this cautionary statement, and Tekmira disclaims any obligation to revise or update any such forward-looking statements or to publicly announce the result of any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments, except as required by law.

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