

**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) **May 21, 2014**

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**Tekmira Pharmaceuticals**

(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 May 21, 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.**

<u>Exhibit</u>	<u>Description</u>
99.1	Press release dated May 21, 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**

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(Registrant)

/s/ **BRUCE G. COUSINS**

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**May 21, 2014**

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(Date)

Bruce G. Cousins

*Executive Vice President and Chief Financial Officer*

## **Tekmira Presents Positive Interim Results on Phase I/II Clinical Programs**

### **Confirms Safety Profile of Third Generation LNP**

VANCOUVER, British Columbia, May 21, 2014 (GLOBE NEWSWIRE) -- Tekmira Pharmaceuticals Corporation (Nasdaq:TKMR) (TSX:TKM), a leading developer of RNA interference (RNAi) therapeutics, announced that recent advances in its clinical programs were presented at the 17<sup>th</sup> Annual Meeting of the American Society of Gene and Cell Therapy, which is taking place in Washington, DC, May 21 to 24.

"Today, Dr. Ian MacLachlan presented positive clinical data which further validates our LNP technology and demonstrates progress within both our anti-viral and oncology programs. The TKM-Ebola phase I trial results are significant as they establish the safety of 'third generation' LNP formulations and confirm that dosing at efficacious levels may be accomplished without the need for pre-medication. We are encouraged by these technology advances and they will support the development of Tekmira's other anti-viral therapeutics," said Dr. Mark J. Murray, Tekmira's President and CEO.

The presentation titled "*Progress in the Development of Lipid Nanoparticle-RNA Therapeutics*" was delivered by Tekmira's Chief Technical Officer, Dr. Ian MacLachlan. During the presentation, Dr. MacLachlan shared new interim data from the ongoing TKM-Ebola Phase I Clinical Trial and the Phase I/II Clinical Trial with TKM-PLK1.

Some key summary points from the presentation include:

#### **TKM-Ebola**

- Tekmira has successfully completed the single ascending dose portion of the TKM-Ebola Phase I Clinical Trial in healthy human volunteers.
- Results demonstrate that administration of the TKM-Ebola therapeutic, in the absence of any steroid containing pre-medication, was well-tolerated at a dose level of 0.3 mg/kg.
- TKM-Ebola drug exposure levels achieved in these subjects demonstrate that the multiple ascending dose portion of the trial will achieve drug exposure levels previously shown to confer complete protection in non-human primates exposed to a lethal Ebola virus inoculum.
- Both the safety profile and pharmacokinetics observed in the single dose portion of the trial support initiation of the multiple ascending dose portion of the study

#### **TKM-PLK1**

- Tekmira previously disclosed (October 2013) three of four Adrenocortical Carcinoma (ACC) patients participating in the company's ongoing GI-NET/ACC trial had achieved stable disease.
- One of these patients is continuing on therapy and has achieved a RECIST qualifying Partial Response (PR), defined as >30% reduction in target tumor lesions.
- This patient with the PR has been on TKM-PLK for 12 months and has experienced a 44% reduction in their target tumor mass, located outside of the liver. Furthermore, scans of the target tumor lesions demonstrate signs of necrosis, indicative of anti-tumor activity.

A copy of Tekmira's presentation from the 17<sup>th</sup> Annual meeting of the American Society of Gene and Cell Therapy will be available on the Tekmira website on the "Events" section at: <http://investor.tekmirapharm.com/events.cfm>.

#### **About RNAi and Tekmira's LNP**

RNAi therapeutics have the potential to treat a broad number of human diseases by "silencing" disease causing genes. The discoverers of RNAi, a gene silencing mechanism used by all cells, were awarded the 2006 Nobel Prize for Physiology or Medicine. RNAi therapeutics, such as "siRNAs," require delivery technology to be effective systemically. Tekmira believes its LNP technology represents the most widely adopted delivery technology for the systemic delivery of RNAi therapeutics. Tekmira's LNP platform is being utilized in multiple clinical trials by both Tekmira and its partners. Tekmira's LNP technology (formerly referred to as stable nucleic acid-lipid particles or SNALP) encapsulates siRNAs with high efficiency in uniform lipid nanoparticles that are effective in delivering RNAi therapeutics to disease sites in numerous preclinical models. Tekmira's LNP formulations are manufactured by a proprietary method which is robust, scalable and highly reproducible, and LNP-based products have been reviewed by multiple FDA divisions for use in clinical trials. LNP formulations comprise several lipid components that can be adjusted to suit the specific application.

#### **About the TKM-Ebola Phase I Clinical Trial**

The TKM-Ebola Phase I clinical trial is a randomized, single-blind, placebo-controlled study involving single ascending doses and multiple ascending doses of TKM-Ebola. The study is assessing the safety, tolerability and pharmacokinetics of administering TKM-Ebola to healthy adult subjects. Tekmira expects to complete the Phase I clinical study in the second half of the year.

### **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).

### **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 our nation's biodefense response capability. For more information, visit [www.jpocbd.osd.mil](http://www.jpocbd.osd.mil).

### **About TKM-PLK1**

Tekmira's lead oncology product candidate, TKM-PLK1, targets polo-like kinase 1 (PLK1), a protein involved in tumor cell proliferation and a validated oncology target. Inhibition of PLK1 expression prevents the tumor cell from completing cell division, resulting in cell cycle arrest and death of the cancer cell. PLK1 has been a target of interest for years, and evidence that patients with elevated levels of PLK1 in their tumors exhibit poorer prognosis and survival rates has been documented in the medical literature. By using an RNAi approach and exploiting its naturally occurring mechanism of action, Tekmira can potentially overcome the limitations of other approaches and effectively silence PLK1.

### **About the TKM-PLK1 Phase I/II Clinical Trial**

The ongoing TKM-PLK1 Phase I/II clinical trial, which is currently targeting GI-NET and ACC patients for enrollment, is a multi-center, single arm, open label study designed to measure efficacy using RECIST and tumor biomarkers for GI-NET patients, as well as to evaluate TKM-PLK1's safety, tolerability and pharmacokinetics. TKM-PLK1, which employs a unique lipid nanoparticle (LNP) formulation for oncology applications, will be administered weekly with each four-week cycle consisting of three once-weekly doses followed by a rest week. It is expected that approximately 20 patients with advanced GI-NET or ACC tumors will be enrolled in this trial, with a minimum of 10 GI-NET patients to be enrolled.

### **About Tekmira**

Tekmira Pharmaceuticals Corporation is a biopharmaceutical company focused on advancing novel RNAi therapeutics and providing its leading lipid nanoparticle 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.

### **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 are generally identifiable by use of the words "believes," "may," "plans," "will," "anticipates," "intends," "budgets," "could," "estimates," "expects," "forecasts," "projects" and similar expressions, and the negative of such expressions. Forward-looking statements in this news release include statements about new interim data from the ongoing TKM-Ebola Phase I Clinical Trial and the Phase I/II Clinical Trial with TKM-PLK1; expectations regarding the completion of the TKM-Ebola Phase I clinical study in the second half of this year; the TKM-Ebola contract with the the U.S. Department of Defense's MCS-BDTX; the ongoing TKM=PLK1 Phase I/II clinical trial with patients with GI-NET or ACC tumors; and Tekmira's strategy, future operations, clinical trials, prospects and the plans of management; RNAi (ribonucleic acid interference) product development programs.

With respect to the forward-looking statements contained in this news release, Tekmira has made numerous assumptions regarding, among other things: LNP's status as a leading RNAi delivery technology; the effectiveness of Tekmira's products as therapeutic treatments for diseases; and mRNA is efficiently delivered using Tekmira's LNP. 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: the ongoing TKM-Ebola Phase I Clinical Trial and the Phase I/II Clinical Trial with TKM-PLK1 may not complete as expected, or at all; Tekmira's products may not prove to be effective as therapeutic treatments for diseases; Tekmira's LNP may not be as efficient of a delivery system for mRNA as currently believed; Tekmira may not obtain and protect intellectual property rights, and operate without infringing on the intellectual property rights of

others; Tekmira may face competition from other pharmaceutical or biotechnology companies and the possibility that other organizations have made advancements in RNAi delivery technology that Tekmira is not aware of; pre-clinical and clinical trials may be more costly or take longer to complete than anticipated and may not generate results that warrant future development of the tested drug candidate; Tekmira's development partners and licensees conducting clinical trial, development programs and joint venture strategic alliances may not result in expected results on a timely basis, or at all; future operating results are uncertain and likely to fluctuate; economic and capital market conditions; Tekmira may become subject to product liability or other legal claims for which Tekmira has made no accrual in its financial statements; and the possibility that Tekmira may not have sufficiently budgeted for expenditures necessary to carry out planned activities.

A more complete discussion of the risks and uncertainties facing Tekmira appears in Tekmira's annual report on Form 10-K for the year ended December 31, 2013 (Annual Report), as well as Tekmira's continuous disclosure filings, which are available at [www.sedar.com](http://www.sedar.com) or at [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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