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# Tekmira Pharmaceuticals Reports 2008 Audited Results and Provides Corporate Update

**Vancouver, BC** — Tekmira Pharmaceuticals Corporation (TSX: TKM) today reported its 2008 audited operating results, including a summary of 2008 corporate and product development achievements and an update on objectives for 2009.

Dr. Mark J. Murray, Tekmira's President and CEO, said, "Over the past year Tekmira has emerged as a leader in the field of RNAi therapeutics as evidenced by our growing list of partners, the advancement of our internal RNAi product candidates and our continued scientific achievements. We expect 2009 to be an important year as we initiate a Phase 1 clinical trial for ApoB SNALP and our partners advance products based on our industry leading SNALP technology."

Key achievements in 2008 and recent highlights include:

- Completion of the business combination between Tekmira Pharmaceuticals Corporation and Protiva Biotherapeutics Inc. that closed May 30, 2008, creating a well funded industry leader in RNAi therapeutics;
- Equity investments by Alnylam Pharmaceuticals, Inc. and the Roche Venture Fund that closed May 30, 2008;
- Advancement of ApoB SNALP through preclinical development and Investigational New Drug (IND) enabling studies as a
  potential treatment for high cholesterol;
- Rigorous research and publication of PLK1 SNALP data in the Journal of Clinical Investigation in February 2009; including preclinical anti-tumor efficacy supporting the advancement of PLK1 SNALP;
- Supporting Alnylam's IND application for ALN-VSP that utilizes Tekmira's SNALP technology. ALN-VSP has received United States Food and Drug Administration (FDA) clearance for initiation of a Phase 1 clinical trial;
- Providing RNAi and SNALP research and development capabilities to a growing list of partners and collaborators, including Alnylam, Roche, Bristol-Myers Squibb, the US Army Medical Research Institute for Infectious Diseases and the United States National Cancer Institute;
- Signing a three year manufacturing alliance with Alnylam to support development of products utilizing Tekmira's SNALP technology. The manufacturing alliance was signed January 2009 and will generate a minimum of \$11.2 million in revenue;
- Continued SNALP technology advances, including improving the therapeutic index 5-10 fold over current formulations, presented at the Asia Tides Conference in Tokyo, Japan in February 2009;
- Expansion of the new Tekmira management team with the additions of Tammy Mullarky as Vice President, Strategic Planning and Business Development and Dr. Peter Lutwyche as Vice President, Pharmaceutical Development; and
- Maintaining a strong balance sheet with \$31.9 million in cash and equivalents as at December 31, 2008.

Dr. Murray added, "We believe we have the technology, scientific expertise, pharmaceutical relationships and product candidates backed by a strong balance sheet to build on our recent progress to provide strong returns for shareholders over the coming years."

# 2009 Corporate Milestones and Update

• Filing of an IND and initiation of a Phase 1 human clinical trial in the first half of 2009 evaluating ApoB SNALP as a treatment for high LDL or "bad cholesterol". ApoB SNALP has been shown in preclinical studies to reduce diet-induced high cholesterol, returning blood cholesterol levels to normal with a single treatment. Tekmira's approach is to address elevated LDL cholesterol by targeting ApoB, a protein synthesized in the liver that plays a central role in transporting cholesterol in the body.

- Advancement of PLK1 SNALP through preclinical development in 2009 to support the filing of an IND in 2010. The IND filing timeline for PLK1 SNALP is being adjusted to allow time to incorporate newly developed SNALP formulation improvements as presented at the Asia Tides Conference in February 2009. These formulation improvements are designed to provide an improved therapeutic index and thereby extend the utility and opportunity for PLK1 SNALP. PLK1 SNALP has been shown in preclinical studies to selectively kill cancer cells, while sparing normal cells in healthy tissue. PLK1 SNALP is targeted against PLK1 (polo-like kinase 1), a protein involved in tumor cell proliferation. Inhibition of PLK1 prevents the tumor cell from completing cell division, resulting in cell cycle arrest and cell death. Recent data published in the peer reviewed Journal of Clinical Investigation highlighted potent anti-tumor efficacy in preclinical models of liver cancer and in models of cancer outside the liver.
- Selection of a third internal RNAi product development candidate. Tekmira has the right to develop a total of seven siRNA products based on access to Alnylam's leading intellectual property in the RNAi field, two of which, ApoB SNALP and PLK1 SNALP, have already been selected.
- Manufacturing of Alnylam's ALN-VSP product candidate that will enter a Phase 1 clinical trial in first half of 2009 as a treatment for liver cancer and other solid tumors with liver involvement.
- Collaborating with other leaders in the RNAi field including Alnylam, Roche, Bristol-Myers Squibb and pharmaceutical and biotechnology companies evaluating RNAi and SNALP technology. Tekmira will continue to provide research and development capabilities to pharmaceutical collaborators as they advance product candidates based on Tekmira's SNALP technology.
- Tekmira will continue to develop novel SNALP formulations to further expand the utility of the platform.
- Maintaining a strong cash position. Tekmira estimates its net monthly cash burn rate for 2009 will be less than \$1.5 million per month and expects its existing cash and revenue from partners will fund the Company's business until the second half of 2010.

# 2008 Financial Results

# Business combination with Protiva on May 30, 2008

On May 30, 2008, Tekmira completed the acquisition of 100% of the outstanding shares of Protiva Biotherapeutics, Inc., a privately owned Canadian company developing lipid nanoparticle delivery technologies for small interfering RNA (siRNA). Concurrent with the business combination with Protiva, Tekmira entered into initial research agreements with F. Hoffman-La Roche Ltd and Hoffman La-Roche Inc. (collectively Roche). Also concurrent with the business combination, the Company completed a private placement investment of 2,083,333 newly issued common shares for \$5.0 million (US\$5.0 million, US\$2.40 per share) with Alnylam Pharmaceuticals, Inc. and a private placement investment of 2,083,333 newly issued common shares for \$5.0 million (\$2.40 per share) with a Roche affiliate. Tekmira believes that the business combination gives it leading scientific capabilities and intellectual property to deliver RNAi therapeutics using its lipid nanoparticle delivery technology which it refers to as SNALP (Stable Nucleic Acid Lipid-Particles).

The Protiva acquisition was accounted for using the purchase method of accounting. The assets and liabilities of Protiva were included in Tekmira's consolidated financial statements from May 30, 2008, the date of acquisition. Total consideration of \$31.8 million, including acquisition costs, was allocated to the assets acquired and liabilities assumed based on preliminary fair values at the date of acquisition resulting in medical technology assets of \$16.3 million and goodwill of \$3.9 million. In valuing Protiva's medical technology Tekmira assumed certain future net positive cash flows from products, both internal and from collaborative relationships, based on this technology. If any of the assumptions underlying Tekmira's valuation of Protiva's medical technology should change then Tekmira will conduct an asset impairment test and may be required to write down the value of this asset.

# **Results of Operations**

For the fiscal year ended December 31, 2008, net loss was \$14.3 million (\$0.35 per common share, basic and fully diluted) as compared to a net loss of \$2.6 million (\$0.11 per common share, basic and fully diluted) for 2007.

There are a number of factors contributing to changes in Tekmira's results including the inclusion of Protiva's results from May 30, 2008, some additional expenses linked to the acquisition of Protiva and an impairment loss on goodwill.

**Revenue** / Revenue from research and development collaborations, licensing fees and milestone payments was \$11.7 million in 2008 as compared to \$15.8 million in 2007. In 2008 most of the Company's revenue was from its partnership with Alnylam whereas in 2007 there was also significant revenue from the Hana partnership. The business combination with Protiva brought in some new collaborative partner revenue streams.

**Alnylam revenue** / During 2007 and 2008 Alnylam reimbursed Tekmira for external costs and the provision of staff for collaborative research, development and manufacturing activities.

Tekmira will continue to provide collaborative research services to Alnylam under a collaborative agreement until August 14, 2009 whereby Alnylam will fund a minimum of US\$2.0 million per annum for the provision of Tekmira research staff. Under a new Manufacturing Agreement dated January 2, 2009, Tekmira will continue to be the exclusive manufacturer of any products required by Alnylam through to the end of phase 2 clinical trials that utilize Tekmira's intellectual property. Alnylam will pay for the provision of staff and for external costs incurred. Under the new Manufacturing Agreement there is a contractual minimum of \$11.2 million in payments from Alnylam to Tekmira for the three years from 2009 to 2011 for the provision of staff.

Under a license agreement Tekmira received an up-front licensing payment of \$9.4 million (US\$8.0 million) from Alnylam. Under a license agreement with the University of British Columbia Tekmira made a milestone payment of \$0.9 million in respect of the up-front payment from Alnylam. The up-front payment and the milestone payment were deferred and were amortized on a straight-line basis to revenue and expense respectively to December 31, 2008, the period over which Tekmira provided research support under that particular agreement.

In December 2008, Alnylam filed an IND application for ALN-VSP, a product candidate that utilizes Tekmira's SNALP technology. Tekmira is eligible to receive a milestone payment from Alnylam upon the dosing of the first patient in an ALN-VSP phase 1 clinical trial which Alnylam expects to occur in the first half of 2009.

**Other RNAi collaborators** / Tekmira has active research agreements with a number of other RNAi collaborators including Bristol-Myers Squibb Company and Roche. Revenue under these agreements is being recognized on a percentage completion basis.

**Expenses / Research and development** / Research and development expenses increased to \$16.1 million in 2008 as compared to \$8.3 million in 2007. Inclusion of Protiva expenses from May 30, 2008, including ApoB SNALP and PLK1 SNALP project expenses and salary and infrastructure costs accounts for \$7.1 million of the increase.

The majority of the increase in research and development external expenditures relate to the ApoB SNALP program, specifically preclinical toxicology costs and costs related to the purchase of GMP materials. Stock based compensation for research and development staff was \$1.3 million in 2008 as compared to \$0.3 million in 2007 as all Tekmira stock options vested concurrent with the announcement of the business combination with Protiva. Intellectual property legal expenses increased by \$0.6 million over the prior year due to the expansion of the Company's patent portfolio following the business combination with Protiva.

Salary and infrastructure costs also increased as a result of the business combination with Protiva. Staff numbers initially increased by about 75% as a result of the business combination although there was a subsequent post-integration reorganization in October. Internal research and development staff numbers were 61 at December 31, 2008 (total staff 76) as compared to 39 (total staff 50) at December 31, 2007.

Research and development expenses are expected to increase in 2009 as the ApoB SNALP program advances through development, the PLK1 SNALP program is advanced into preclinical toxicology studies and the Company continues to incur collaboration costs that will be passed through to collaborative partners.

**General and administrative** / General and administrative expenses were \$4.4 million for 2008 as compared to \$4.4 million for 2007. There were a number of off-setting changes in the composition of general and administrative expenses. Protiva expenses from May 30, 2008, the date of business combination, were \$0.7 million. Stock based compensation for general and administrative staff was \$0.4 million in 2008 as compared to \$0.1 million in 2007 and in line with the increase noted above. Legal and professional fees were substantial in 2007 as the Company worked to complete the corporate reorganization on April 30, 2007. Legal and professional fees were similarly higher than normal in the period up to completion of the business combination with Protiva but these fees have been capitalized as they are a cost of acquisition of Protiva.

General and administrative expenses are expected to be slightly lower in 2009 than 2008 and 2007, as the past two years have included a number of one time expenses.

**Termination and restructuring expenses** / Termination and restructuring expenses were \$3.2 million in 2008 and \$nil in 2007. In May 2008, as a condition of closing the business combination with Protiva, the employment contract of Tekmira's Chief Executive Officer was terminated and an expense of \$2.0 million was recorded. In October 2008, as part of the integration of the operations of Tekmira and Protiva, there was a restructuring that resulted in a reduction in workforce of 15 employees and an expense of \$1.2 million.

Impairment loss on goodwill / In response to the recent down-turn in financial markets the Company carried out a goodwill

impairment test as at September 30, 2008. Based on Tekmira's market capitalization as at September 30, 2008 it was determined that the fair value of goodwill arising from the acquisition of Protiva was nil and an impairment loss of \$3.9 million, the full value of goodwill, was recorded in the Consolidated statement of operations and comprehensive loss.

**Foreign exchange and other gains (losses)** / Foreign exchange and other gains (losses) showed gains of \$2.1 million for 2008 as compared to losses of \$1.0 million for 2007. The foreign exchange gains in 2008 relate largely to the positive effect on US denominated cash investments and accounts receivable from the strengthening of the US dollar as compared to the Canadian dollar. A weakening US dollar in 2007 had the opposite effect.

Towards the end of 2008 Tekmira converted the majority of its US dollar cash and cash equivalent holdings into Canadian dollars to reduce its future exposure to foreign exchange rate fluctuations. However, as a large portion of revenues and expenses are in US dollars, exchange rate fluctuations will continue to create gains or losses as the Company expects to continue holding US denominated cash, cash investments, accounts receivable and accounts payable.

#### **Liquidity and Capital Resources**

At December 31, 2008, Tekmira had cash, cash equivalents and short-term investments of approximately \$31.9 million as compared to \$20.9 million at December 31, 2007.

The Company believes that current funds on hand plus expected interest income and the contractually payable further funds from Alnylam and other collaborators will be sufficient to continue product development until some time in the second half of 2010.

# About RNAi and SNALP

RNAi drugs have the potential to treat human diseases by "switching-off" disease causing genes. The technology, representing one of the most promising and rapidly advancing frontiers in biology and drug discovery, was awarded the 2006 Nobel Prize for Physiology or Medicine. RNAi drugs, such as siRNA, require delivery technology to be administered systemically. In preclinical studies, Tekmira's SNALP (stable nucleic acid-lipid particles) technology has been shown to be a safe and effective way to deliver RNAi drugs to disease sites. Tekmira believes it has a leading intellectual property position in the field of siRNA delivery.

#### **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. Further information about Tekmira can be found at <u>www.tekmirapharm.com</u>. Tekmira is based in Vancouver, B.C.

#### **Forward-Looking Statements and Information**

There are forward-looking statements and information contained herein that are not based on historical fact, including, without limitation, statements containing the words "believes," "may," "plans," "will," "estimate," "continue," "anticipates," "intends," "expects," and similar expressions, and the negative of such expressions. These statements are only predictions.

Forward-looking statements and information should be considered carefully. Undue reliance should not be placed on forward-looking statements and information as there can be no assurance that the plans, intentions or expectations upon which they are based will occur. By their nature, forward-looking statements and information involve numerous assumptions, known and unknown risks and uncertainties, both general and specific, which contribute to the possibility that the predictions, forecasts, projections and other forward-looking statements and information will not occur and may cause actual results or events to differ materially from those anticipated in such forward-looking statements and information.

Within the next several years, Tekmira's believes that substantial additional funds will be required to continue with the active development of its pipeline products and technologies. Tekmira's assumption that its cash resources are sufficient to maintain operations until the second half of 2010 is based, in particular, on assumptions involving the following:

- revenues earned from collaborative partnerships, particularly Alnylam;
- decisions to in-license or acquire additional products for development, in particular for Tekmira's RNAi therapeutics program;
- the extent to which Tekmira continues development or can extract significant value from its technologies;
- Tekmira's ability to attract and retain corporate partners, and their effectiveness in carrying out the development and ultimate commercialization of its product candidates;
- the decisions, and the timing of decisions, made by health regulatory agencies regarding Tekmira's technology and products;
- · competing technological and market developments; and

• prosecuting and enforcing patent claims and other intellectual property rights.

More particularly and without limitation, this discussion and analysis contains forward-looking statements and information concerning the potential of Tekmira; the potential of RNAi therapeutics as a treatment for disease; and the number and timing of advancement of its products into clinical development.

There are also other factors that may cause the actual results, events or developments to be materially different from any future results, events or developments expressed or implied by such forward-looking statements and information. Such factors include, among others, the stage of development of Tekmira, lack of product revenues, additional capital requirements, the impact of the global economic downturn, the need to obtain regulatory approval to commence clinical trials, risks associated with the completion of clinical trials and obtaining regulatory approval to market Tekmira's products, the safety and efficacy of Tekmira's products, the ability to protect Tekmira's intellectual property and dependence on collaborative partners.

A more complete discussion of the risks and uncertainties facing Tekmira appears in Tekmira's management information circular dated May 1, 2008 available at <u>www.sedar.com</u>. Tekmira disclaims any obligation to update any such factors or to publicly announce the result of any revisions to any of the forward-looking statements or information contained herein to reflect future results, events or developments, except as required by law.

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