Aeterna Zentaris Reports Third Quarter 2021 Financial Results and Provides Pipeline Program Updates

- Company continues to build strong developmental pipeline

- Supported by solid cash position

TORONTO, ONTARIO, Nov. 04, 2021 (GLOBE NEWSWIRE) -- Aeterna Zentaris Inc. (NASDAQ: AEZS) (TSX: AEZS) ("Aeterna" or the "Company"), a specialty biopharmaceutical company developing and commercializing a diversified portfolio of pharmaceutical and diagnostic products, today reported its financial and operating results for the third quarter ended September 30, 2021. The Company also provided an update on progress in its pre-clinical and clinical development programs.

"Since January 2021, we have made a concerted effort to not only advance our clinical-stage program but to expand our development pipeline. We have delivered on that goal and are pleased with the progress made to date. The leadership and expertise we have established at Aeterna Zentaris, now coupled with a diversified portfolio of assets with the potential to address areas of significant medical need, has created an exciting time in the Company's evolution and multiple potential avenues for value creation. We are diligently working to execute on the advancement of all our clinical and pre-clinical programs and are poised to continue building momentum and value in the near and long term," commented Dr. Klaus Paulini, Chief Executive Officer of Aeterna.

Recent Highlights:

- Entered into an additional exclusive license with the Julius-Maximilians-University of Wuerzburg (the "University of Wuerzburg") for early pre-clinical development of AIM Biologics for the potential treatment of Parkinson's disease.
- Exercised its option under the agreement with the University of Wuerzburg to expand application of oral vaccine platform to second indication, chlamydia.

Pre-Clinical and Clinical Programs Update:

Diagnostics Development Pipeline

Macimorelin Diagnostic: *Ghrelin agonist in development for diagnostic use in childhood-onset growth hormone deficiency ("CGHD")*

Aeterna is currently conducting its pivotal Phase 3 safety and efficacy study AEZS-130-P02 (the "DETECT-trial") evaluating macimorelin for the diagnosis of CGHD. Children and adolescents from two to less than 18 years of age with suspected growth hormone deficiency are to be included. The study is expected to include approximately 100 subjects worldwide, with at least 40 subjects in pre-pubertal and 40 subjects in pubertal status. Macimorelin growth hormone stimulation test ("GHST") will be performed twice for repeatability data and two standard GHSTs will be used as controls: arginine (i.v.) and clonidine (p.o.). On April 22, 2021, the U.S. FDA Investigational New Drug Application associated with this clinical trial became active. The first clinical sites in the U.S. are open for patient recruitment. In the EU and rest of world countries, clinical trial approval procedures and site initiation activities are ongoing.

Next Steps

- Conduct and complete the DETECT-trial.

Therapeutics and Vaccine Development Pipeline

AIM Biologicals: *Targeted, highly specific autoimmunity modifying therapeutics for the potential treatment of neuromyelitis optica spectrum disorder ("NMOSD") and Parkinson's disease (PD)*

In January 2021, Aeterna entered into an exclusive patent license and research agreement with the University of Wuerzburg, Germany, for worldwide rights to develop, manufacture and commercialize AIM Biologicals for the potential treatment of NMOSD. Additionally, the Company has engaged Prof. Dr. Joerg Wischhusen of the University of Wuerzburg as well as neuro-immunologist Dr. Michael Levy (MGH/Boston) as consultants, who will provide scientific support and advice in the field of inflammatory CNS disorders, autoimmune diseases of the nervous system, and NMOSD.

In September 2021, the Company entered into an additional exclusive license with the University of Wuerzburg for early pre-clinical development for the potential treatment of Parkinson's disease.

Next Steps - NMOSD

- Conduct *in-vitro* and *in-vivo* assessments to select an AIM Biologicals-based development candidate.
- Manufacturing process development for selected candidate.

Next Steps - Parkinson's Disease

- Design and produce antigen-specific AIM Biologics molecules for the potential treatment of Parkinson's disease.
- Conduct *in-vitro* and *in-vivo* assessments in relevant Parkinson's disease models.

Macimorelin Therapeutic: *Ghrelin agonist in development for the treatment of ALS (Lou Gehrig's disease)*

In January 2021, the Company entered into a material transfer agreement with the University of Queensland, Australia, to provide macimorelin for the conduct of pre-clinical and subsequent clinical studies evaluating macimorelin as a potential therapeutic for the treatment of ALS (Lou Gehrig's disease). The University of Queensland researchers have filed for supportive grants and aim to conduct pre-clinical studies in multiple pre-clinical models to demonstrate the therapeutic reach of macimorelin on disease progression and disease-specific pathology. They also plan to conduct a subsequent investigator initiated clinical trial given positive pre-clinical results.

Macimorelin, a ghrelin agonist, is an orally active small molecule that stimulates the secretion of growth hormone from the pituitary gland. Acting via this mechanism, it is believed that macimorelin may slow the progression of certain neurodegenerative diseases like ALS.

Next Steps

- Work with the University of Queensland to conduct proof-of-concept studies with macimorelin in disease-specific animal models.
- Assess alternative formulations.
- Formalize pre-clinical development plan.

Delayed Clearance Parathyroid Hormone ("DC-PTH") Fusion Polypeptides: *Potential treatment for primary hypoparathyroidism*

In March 2021, Aeterna entered into an exclusive patent and know-how license agreement and research agreement with The University of Sheffield, United Kingdom, for the intellectual property relating to DC-PTH fusion polypeptides with delayed clearance for all human uses. In consultation with The University of Sheffield, Aeterna has selected AEZS-150 as the lead candidate in its DC-PTH program. AEZS-150 is being developed with the goal of providing a potential new treatment option of primary hypoparathyroidism in adults.

Next Steps

- Work with The University of Sheffield to conduct in depth characterization of development candidate (*in-vitro* and *in-vivo*).
- Develop manufacturing process.
- Formalized pre-clinical development of AEZS-150 in preparation for a potential IND filing for conducting the first in-human clinical study.

Vaccine Platform: *Potential orally active, live-attenuated bacterial vaccine with application across multiple coronavirus types, including COVID-19 (SARS-CoV-2) and chlamydia*

In February 2021, Aeterna entered into an exclusive option agreement with the University of Wuerzburg to evaluate a pre-clinical, potential COVID-19 vaccine developed at the University of Wuerzburg. In March 2021, the Company exercised its option and entered into a license agreement where the Company was granted an exclusive, world-wide, license to certain patent applications and know-how owned by the University of Wuerzburg to research and develop, manufacture, and sell a potential COVID-19 vaccine. The Company's vaccine platform is currently undergoing pre-clinical studies for the prevention of coronavirus diseases, including COVID-19 (SARS-CoV-2) with the planned start of clinical development targeted for H1 2023.

In September 2021, the Company exercised its option under the agreement with the University of Wuerzburg on a then undisclosed field, now known to be chlamydia. *Chlamydia trachomatis* is a sexually transmitted bacterium infecting over 130 million subjects annually. Asymptomatic disease can spread to the reproductive tract eventually inducing infertility, miscarriage, or ectopic pregnancy, which is a life-threatening condition. Ocular infections can lead to inclusion conjunctivitis or trachoma, which is the primary source of visual impairment or infectious blindness.

Additionally, the Company has entered into a Research Agreement under which the Company has engaged the University of Wuerzburg on a fee-for-service basis to conduct supplementary research activities and pre-clinical development studies on the potential vaccines, the results of which will be included within the scope of the license agreements. Additionally, Prof. Dr. Thomas Rudel of the University of Wuerzburg was engaged by the Company in September 2021 as a scientific consultant to support development of the salmonella-based vaccine platform for the coronavirus and chlamydia vaccines.

Next Steps - Coronavirus Vaccine

- Evaluate administration route, dose and immunization scheme.
- *In-vivo* immunology experiments with antigen variant candidates in relevant mice models.
- Conduct virus challenge experiments in immunized transgenic animals.
- Start manufacturing process assessment / development.
- Conduct pre-clinical safety and toxicology assessment.

Next Steps - Chlamydia Vaccine

- Design and prepare candidate vaccine strains.
- Evaluate administration route, dose and immunization scheme.
- *In-vivo* immunology experiments with candidate strains in relevant mouse models.

Summary of Third Quarter 2021 Financial Results

All amounts in this press release are in U.S. dollars unless otherwise noted.

Financing and Warrant Exercises

During the period between January 1, 2021, and September 30, 2021, holders have exercised certain of our outstanding warrants to purchase 35,011,187 of the Company's common shares for gross proceeds of approximately $20.0 million. On October 1, 2021, the Company received notice of exercise of 100,000 warrants at $0.45 per common share for the issuance of 100,000 common shares of the Company; such exercise was completed on October 4, 2021.

Cash and cash equivalents

The Company had $68.0 million in cash and cash equivalents at September 30, 2021 (June 30, 2021 - $69.9 million).

Results of operations for the three-month period ended September 30, 2021

For the three-month period ended September 30, 2021, the Company reported a consolidated net loss of $1.7 million, or $0.01 loss per common share (basic), as compared with a consolidated net loss of $1.1 million, or $0.02 loss per common share (basic) for the three-month period ended September 30, 2020. The $0.6 million increase in net loss is primarily from an increase in total operating expenses of $0.6 million and a decline in net finance income of $0.5 million, partially offset by an increase of $0.5 million in total revenue.

Revenues

- Total revenue for the three-month period ended September 30, 2021, was $0.6 million as compared with $0.1 million for the same period in 2020, representing an increase of $0.5 million. 2021 revenue was comprised of $0.52 million in licensing revenue (2020 - $0.02 million), $0.06 million in supply chain revenue (2020 - $0.09 million) and $0.02 million in royalty income (2020 - $0.02 million).

Operating expenses

- The Company's total operating expenses for the three-month period ended September 30, 2021, were $2.4 million as compared with $1.9 million for the same period in 2020, representing an increase of $0.5 million. This increase arose primarily from a $0.4 million increase in research and development costs and an increase of $0.1 million in selling expenses. This increase in total operating expenses was primarily due to the impact of the initiation of research and development projects as announced in the first quarter of 2021.

Net finance income

- Net finance income for the three-month period ended September 30, 2021, was $0.1 million as compared with net finance income of $0.6 million for the same period in 2020, representing a decrease in net finance income of $0.5 million. This was primarily due to the $0.8 million decrease in the change in fair value of the warrant liability and a $0.1 million decline in the gain from changes in foreign currency exchange rates partially offset by a $0.4 million reduction in other finance costs.

Consolidated Financial Statements and Management's Discussion and Analysis

For reference, the Management's Discussion and Analysis of Financial Condition and Results of Operations for the third quarter of 2021, as well as the Company's unaudited consolidated interim financial statements as of September 30, 2021, will be available on the Company's website (www.zentaris.com) in the Investors section or at the Company's profile at www.sedar.com and www.sec.gov.

About Aeterna Zentaris Inc.

Aeterna Zentaris is a specialty biopharmaceutical company developing and commercializing a diversified portfolio of pharmaceutical and diagnostic products focused on areas of significant unmet medical need. The Company's lead product, macimorelin (Macrilen™), is the first and only U.S. FDA and European Commission approved oral test indicated for the diagnosis of adult growth hormone deficiency (AGHD). The Company is leveraging the clinical success and compelling safety profile of macimorelin to develop it for the diagnosis of childhood-onset growth hormone

deficiency (CGHD), an area of significant unmet need, in collaboration with Novo Nordisk.

Aeterna Zentaris is dedicated to the development of therapeutic assets and has recently taken steps to establish a growing pre-clinical pipeline to potentially address unmet medical needs across a number of indications, including neuromyelitis optica spectrum disorder (NMOSD), Parkinson's disease (PD), hypoparathyroidism and amyotrophic lateral sclerosis (ALS; Lou Gehrig's disease). Additionally, the Company is developing an oral prophylactic bacterial vaccine against SARS-CoV-2 (COVID-19) and chlamydia.

For more information, please visit www.zentaris.com and connect with the Company on Twitter, LinkedIn and Facebook.

Forward-Looking Statements

This press release contains statements that may constitute forward-looking statements within the meaning of U.S. and Canadian securities legislation and regulations and such statements are made pursuant to the safe-harbor provision of the U.S. Securities Litigation Reform Act of 1995. Forward-looking statements are frequently, but not always, identified by words such as "expects," "anticipates," "believes," "intends," "potential," "possible," and similar expressions. Such statements, based as they are on current expectations of management, inherently involve numerous risks, uncertainties and assumptions, known and unknown, many of which are beyond our control. Forward-looking statements in this press release include, but are not limited to, those relating to: Aeterna's expectations with respect to the DETECT-trial (including regarding the enrollment of subjects in the DETECT-trial, the application of the Macimorelin growth hormone stimulation tests and the completion of the DETECT-trial); Aeterna's expectations regarding conducting pre-clinical research to identify and characterize an AIM Biologicals-based development candidate for the treatment of NMOSD as well as Parkinson's disease, and developing a manufacturing process for a selected candidates; Aeterna's expectations regarding conducting assessments in relevant Parkinson's disease models; The University of Queensland undertaking a subsequent investigator initiated clinical trial evaluating macimorelin as a potential therapeutic for the treatment of ALS and Aeterna formulating a pre-clinical development plan for same; the commencement of Aeterna's formal pre-clinical development of AEZS-150 in preparation for a potential IND filing for conducting the first in-human clinical study of AEZS-150; Aeterna's plans to perform challenge experiments, select a development candidate, start clinical development and establish a manufacturing process for the orally active COVID-19 (SARS-CoV-2) and chlamydia live-attenuated bacterial vaccine.

Forward-looking statements involve known and unknown risks and uncertainties, and other factors which may cause the actual results, performance or achievements stated herein to be materially different from any future results, performance or achievements expressed or implied by the forward-looking information. Such risks and uncertainties include, among others, our reliance on the success of the pediatric clinical trial in the European Union and U.S. for Macrilen™ (macimorelin); the commencement of the DETECT-trial may be delayed or we may not obtain regulatory approval to initiate that study; we may be unable to enroll the expected number of subjects in the DETECT-trial and the result of the DETECT-trial may not support receipt of regulatory approval in CGHD; the coronavirus vaccine platform technology (and any vaccine candidates using that technology) licensed from the University of Wuerzburg has never been tested in humans and so further pre-clinical or clinical studies of that technology and any vaccine developed using that technology may not be effective as a vaccine against COVID-19 (SARS-CoV-2) or any other coronavirus disease; the timeline to develop a vaccine may be longer than expected; such technology or vaccines may not be capable of being used orally, may not have the same characteristics as vaccines previously approved using the Salmonella Typhi Ty21a carrier strain; results from ongoing or planned pre-clinical studies of macimorelin by the University of Queensland or for our other products under development may not be successful or may not support advancing the product to human clinical trials; our ability to raise capital and obtain financing to continue our currently planned operations; our now heavy dependence on the success of Macrilen™ (macimorelin) and related out-licensing arrangements and the continued availability of funds and resources to successfully commercialize the product, including our heavy reliance on the success of the license agreement and the amended license agreement (collectively the Novo Amended License Agreement); the global instability due to the global pandemic of COVID-19, and its unknown potential effect on our

planned operations; our ability to enter into out-licensing, development, manufacturing, marketing and distribution agreements with other pharmaceutical companies and keep such agreements in effect; and our ability to continue to list our common shares on the NASDAQ. Investors should consult our quarterly and annual filings with the Canadian and U.S. securities commissions for additional information on risks and uncertainties, including those risks discussed in our Annual Report on Form 40-F and annual information form, under the caption "Risk Factors". Given the uncertainties and risk factors, readers are cautioned not to place undue reliance on these forward-looking statements. We disclaim any obligation to update any such factors or to publicly announce any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments, unless required to do so by a governmental authority or applicable law.

No securities regulatory authority has either approved or disapproved of the contents of this news release. The Toronto Stock Exchange accepts no responsibility for the adequacy or accuracy of this release.

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