

Aeterna Zentaris Inc.

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Press Release

For immediate release

Aeterna Zentaris Reports Third Quarter 2019 Financial and Operating Results

CHARLESTON, S.C., November 7, 2019 (GLOBE NEWSWIRE) - Aeterna Zentaris Inc. (NASDAQ: AEZS) (TSX: AEZS) today reported its financial and operating results for the third quarter ended September 30, 2019.

All Amounts are in U.S. Dollars

Highlights

- Net loss for the third quarter of 2019 was \$0.3 million as compared to net loss of \$2.5 million for the same period in 2018. Net loss for the nine-months ended September 30, 2019 was \$5.0 million as compared to net income of \$9.3 million for the same period in 2018.
- As of September 30, 2019, we had \$10.9 million of unrestricted cash and cash equivalents.
- On September 20, 2019, the Company entered into a securities purchase agreement with U.S. institutional investors to purchase \$5.0 million (before transaction costs of \$0.8 million) of its common shares in a registered direct offering and warrants to purchase common shares in a concurrent private placement. The combined purchase price for one common share and one warrant was \$1.50. Under the terms of the securities purchase agreement, the Company sold 3,325,000 common shares. In a concurrent private placement, the Company issued warrants to purchase up to an aggregate of 3,325,000 common shares. The warrants are exercisable commencing six months from the date of issuance, have an exercise price of \$1.65 per share and expire 5 years following the date of issuance.
- The Company earned royalty income for the nine-month period ending September 30, 2019 of \$0.03 million from the license of Macrilen™ (macimorelin) and we invoiced Novo Nordisk (Novo) \$0.8 million for its share of our pediatric clinical study (the “PIP study”) costs and \$1.1 million for supply chain costs.
- During the third quarter of 2019, Novo confirmed that it had initiated a thorough review on support, reimbursement, distribution and marketing arrangements regarding Macrilen™ (macimorelin) in order to identify improvements to the Macrilen™ commercialization plans. We continue to work with Novo on addressing the slower than expected U.S. sales to date.

- The initial phase of the Macrilen™ macimorelin PIP study (the “P01 Dose Ranging Study”) continued to progress with the first two-thirds of subjects having completed the protocol. We currently expect to complete the P01 Dose Ranging Study in the first quarter of 2020.

Summary of Third Quarter Results and Year-to-date Third Quarter Results

For the three-month period ended September 30, 2019, we reported a consolidated net loss of \$0.3 million, or \$0.02 loss per common share (basic), as compared with a consolidated net loss of \$2.5 million, or \$0.15 loss per common share, for the three-month period ended September 30, 2018. The \$2.2 million improvement in net results is primarily from a gain in fair value of warrant liability of \$2.1 million and a decline in operating expenses of \$1.1 million and an increase in gross income of \$0.1 million and \$0.1 million increase in foreign currency exchange rates, offset by \$0.5 million movement in tax recovery and an increase in net finance costs of \$0.7 million.

For the nine-month period ended September 30, 2019, we reported a consolidated net loss of \$5.0 million, or \$0.31 loss per common share, as compared with a consolidated net income of \$9.3 million, or \$0.57 income per common share (basic), for the nine-month period ended September 30, 2018. The \$14.3 million decline in net results is primarily from a reduction of \$24.3 million in gross income offset by \$6.1 million in tax expense, \$3.0 million decline in operating expenses and \$0.9 million increase in net finance income.

On June 6, 2019, the Company announced that it was reducing the size of its German workforce and operations to more closely reflect the Company’s ongoing commercial activities in Frankfurt. This restructuring affects 8 employees in Frankfurt, Germany and resulted in \$0.8 million of severance costs that are expected to be paid by January 31, 2020.

In July 2019, Michael Ward resigned as managing director of AEZS Germany and Dr. Klaus Paulini assumed this role. In August 2019, Jonathan Pollack resigned as a director of Aeterna Zentaris Inc. and, in September 2019, Brian Garrison, resigned as a Senior Vice President, Global Commercial Operations of Aeterna Zentaris Inc. Subsequent to quarter-end, on October 4, 2019, Dr. Klaus Paulini was announced as President and Chief Executive Officer of the Company, replacing Michael Ward who is entitled to severance of approximately \$0.5 million. Dr. Paulini was also appointed as a Director of Aeterna Zentaris Inc. at that time.

Condensed Interim Consolidated Financial Statements and Management’s Discussion and Analysis

For reference, the condensed interim consolidated financial statements as at September 30, 2019 and for the three-month and nine-month periods ending September 30, 2019 and 2018 and management’s discussion and analysis of financial condition and results of operations three-month and nine-month periods ending September 30, 2019, will be found at www.zentaris.com in the "Investors" section and at the Company’s profile at www.sedar.com and www.sec.gov.

The following tables set out summary consolidated financial information for the periods indicated. The results of operations for interim periods are not necessarily indicative of the results to be expected for a full year or any future period. The information presented herein does not contain disclosures required by IFRS for consolidated financial statements and should be read in conjunction with the Company’s audited annual consolidated financial statements for the year ended December 31, 2018.

About Aeterna Zentaris Inc.

Aeterna Zentaris Inc. is a specialty biopharmaceutical company engaged in commercializing novel pharmaceutical therapies, principally through out-licensing arrangements. Aeterna Zentaris is the licensor and party to a license and assignment agreement with Novo Nordisk A/S to carry out development, manufacturing, registration, regulatory, and supply chain for the commercialization of Macrilen™ (macimorelin), which is to be used in the diagnosis of patients with adult growth hormone deficiency in the United States and Canada. In addition, we are actively pursuing business development opportunities for macimorelin in the rest of the world and to monetize the value of our non-strategic assets.

Forward-Looking Statements

This press release contains forward-looking statements (as defined by applicable securities legislation) made pursuant to the safe-harbor provision of the U.S. Securities Litigation Reform Act of 1995, which reflect our current expectations regarding future events. Forward-looking statements may include, but are not limited to statements preceded by, followed by, or that include the words "will," "expects," "believes," "intends," "would," "could," "may," "anticipates," and similar terms that relate to future events, performance, or our results. Forward-looking statements involve known and unknown risks and uncertainties, including those discussed in this press release and in our Annual Report on Form 20-F, under the caption "Key Information -Risk Factors" filed with the relevant Canadian securities regulatory authorities in lieu of an annual information form and with the U.S. Securities and Exchange Commission. Known and unknown risks and uncertainties could cause our actual results to differ materially from those in forward-looking statements. Such risks and uncertainties include, among others, our ability to continue as a going concern dependent, in part, on the ability of Aeterna Zentaris to transfer cash from Aeterna Zentaris GmbH to the Canadian parent and U.S. subsidiary and secure additional financing, 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, our strategic review process, the ability of the Special Committee to carry out its mandate, the ability of Aeterna Zentaris to enter into out-licensing, development, manufacturing and marketing and distribution agreements with other pharmaceutical companies and keep such agreements in effect, reliance on third parties for the manufacturing and commercialization of Macrilen™ (macimorelin), potential delay or termination of our pediatric clinical trial program, potential disputes with third parties, leading to delays in or termination of the manufacturing, development, out-licensing or commercialization of our product candidates, or resulting in significant litigation or arbitration, and, more generally, uncertainties related to the regulatory process, our ability to efficiently commercialize or out-license Macrilen™ (macimorelin), the degree of market acceptance of Macrilen™ (macimorelin), our ability to obtain necessary approvals from the relevant regulatory authorities to enable us to use the desired brand names for our product, the impact of securities class action litigation or other litigation on our cash flow, results of operations and financial position, our ability to take advantage of business opportunities in the pharmaceutical industry, our ability to protect our intellectual property, the potential of liability arising from shareholder lawsuits and general changes in economic conditions. Investors should consult our quarterly and annual filings with the Canadian and U.S. securities commissions for additional information on risks and uncertainties. Given these 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.

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Condensed Interim Consolidated Statements of Comprehensive (Loss) Income

	Three months ended September 30,		Nine months ended September 30,	
(in thousands, except share and per share data)	2019	2018	2019	2018
	\$	\$	\$	\$
Revenues				
Royalty income	8	—	29	—
Product sales	—	663	129	721
Sales commission and other	256	—	301	721
Licensing revenue	19	—	55	24,657
Total revenues	283	663	514	24,489
Cost of goods sold	—	494	101	691
Gross income	283	169	413	24,798
Research and development costs	475	358	1,574	2,165
General and administrative expenses	1,364	2,439	4,924	7,229
Selling expenses	377	383	1,176	2,521
Restructuring costs	—	—	773	—
Impairment (reversal) of right of use asset	(125)	—	276	—
Write-off of other current assets	—	—	169	—
Total operating expenses	2,091	3,180	8,892	11,915
(Loss) income from operations	(1,808)	(3,011)	(8,479)	12,883
Gain (loss) due to changes in foreign currency exchange rates	3	(133)	61	592
Change in fair value of warrant liability	2,120	58	3,985	1,752
Other finance (costs) income	(646)	30	(603)	174
Net finance (costs) income	1,477	(45)	3,443	2,518
Income (loss) before income taxes	(331)	(3,056)	(5,036)	15,401
Income tax recovery (expense)	—	547	—	(6,088)
Net (loss) income	(331)	(2,509)	(5,036)	9,313
Other comprehensive (loss) income:				
Foreign currency translation adjustments	377	3	351	(247)
Actuarial (gain) loss on defined benefit plans	(536)	406	(2,027)	611
Comprehensive (loss) income	(490)	(2,100)	(6,712)	9,677
Net (loss) income per share [basic]	(0.02)	(0.15)	(0.31)	0.57
Net (loss) income per share [diluted]	(0.02)	(0.15)	(0.31)	0.56
Weighted average number of shares outstanding:				
Basic	16,887,819	16,440,760	16,651,969	16,440,760
Diluted	16,887,819	16,440,760	16,651,969	16,655,576

Condensed Interim Consolidated Statement of Financial Position

(in thousands)

	As at September 30, 2019	As at December 31, 2018
	\$	\$
Cash and cash equivalents	10,862	14,512
Trade and other receivables and other current assets	1,349	1,504
Inventory	582	240
Restricted cash equivalents	356	418
Property, plant and equipment	42	65
Right of use asset	418	—
Other non-current assets	7,893	8,272
Total assets	21,502	25,011
Payables and other current liabilities	2,908	2,966
Current portion of deferred revenues	74	74
Warrant liability	2,788	3,634
Current provision for restructuring costs and other costs	877	887
Taxes payable	1,595	1,669
Employee future benefits	14,477	13,205
Lease liabilities	408	—
Non-current portion of restructuring and other costs and deferred revenues	568	669
Total liabilities	23,695	23,104
Shareholders' (deficiency) equity	(2,193)	1,907
Total liabilities and shareholders' (deficiency) equity	21,622	25,011