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Aeterna Zentaris Reports First Quarter 2018 Financial and Operating Results

CHARLESTON, S.C., May 7, 2018 (GLOBE NEWSWIRE) - Aeterna Zentaris Inc. (NASDAQ:AEZS) (TSX:AEZS) today reported financial and operating results for the first quarter ended March 31, 2018.

All Amounts are in U.S. Dollars

Recent Key Developments

- *Continue to exceed terms of licensing and assignment agreement with Strongbridge Ireland Limited in support of its Macrilen™ (macimorelin) commercial launch in the U.S.* targeted for *summer of 2018*
- *Diligently prepare European Medicines Agency (EMA) D120 regulatory response to Marketing Authorization Application (MAA) of macimorelin for anticipated submission in July 2018*
- *Actively seeking out-licensing partners for macimorelin in Europe*
- *Expanding resources to actively assist in identifying potential marketed products in the U.S. market*
- *Financial condition and capital structure significantly improved*
    - *Upfront payment of $24 million received from Strongbridge in January 2018;*
    - *As of March 31, 2018, $24.5 million of unrestricted cash and cash equivalents;*
    - *Approximately 16.4 million Common Shares outstanding as of March 31, 2018*

Financial Highlights

- *Revenues $24.7 million*
- *Research and Development ("R&D") Costs $0.8 million*
- *General and Administrative ("G&A") Expenses $2.8 million*
- *Selling Expenses $1.6 million*
- *Net Finance Income $1.9 million*
- *Income Taxes $6.9 million*
- *Net Income $14.4 million*
- *Working Capital $19.6 million*

Commenting on recent key developments, Michael V. Ward, President and Chief Executive Officer for Aeterna Zentaris, stated, "We ended first quarter 2018 in the strongest financial position in the past decade. Our licensing agreement of Macrilen™ (macimorelin) in the U.S. and Canada with Strongbridge demonstrates the success of our development initiatives and better positions us to monetize our rights by licensing in territories outside of the United States and Canada."

First Quarter Highlights

Revenues

Licensing revenue was $24.6 million for the three months ended March 31, 2018, as compared to $0.1 million for the same period in 2017. The increase is primarily due to the recognition in January 2018, of the $24.0 million upfront payment received from Strongbridge for the license of Macrilen™(macimorelin) as earned revenue in accordance with International Financial Reporting Standards (IFRS) 15, Revenue from Contracts with Customers as it is a "right to use" license. In addition, due to events that occurred in 2018, we consider our performance obligations under the Zoptrex™ licensing agreements to be fulfilled, therefore we recognized deferred revenues of $0.5 million relating to non-refundable upfront payments it previously received for licensing and technology transfer arrangements that it entered into with respect to the development of Zoptrex™ in various territories.

Sales commission and other were $90,000 for the three months ended March 31, 2018, compared to $153,000 for the same period in 2017. During 2018, we received a $90,000 termination agreement payment from our customer. In 2017, those revenues mainly resulted from our sales team exceeding pre-established unit sales baseline thresholds under our co-promotion agreement to sell Saizen®. We also generated sales commission in connection with our promotion of APIFINY®.

Operating Expenses

R&D costs were $0.8 million for the three months ended March 31, 2018, as compared to $2.5 million for the same period in 2017. The decrease in R&D costs is mainly attributable to lower comparative third-party costs.

Additionally, the decrease in our R&D costs for the three months ended March 31, 2018, as compared to the same period in 2017, is attributable to lower employee compensation and benefits costs, as well as lower facilities rent and maintenance costs. A substantial portion of this decrease is due to the realization of cost savings in connection with our ongoing efforts to streamline our R&D activities.

Third-party costs attributable to Zoptrex™ and Macrilen™ (macimorelin) decreased considerably during the three months ended March 31, 2018 as compared to March 31, 2017, mainly since we completed the clinical portion of the ZoptEC trial and the Macrilen™ (macimorelin) trial in 2017 and 2016, respectively. Third-party costs attributable to Macrilen™ (macimorelin) incurred in 2017 are related to the detailed analysis of the results as well as the preparation of the New Drug Application filing, which was submitted on June 30, 2017.

Excluding the impact of foreign exchange rate fluctuations, we expect that we will incur overall R&D costs of between $1.0 million and $2.0 million for the year ended December 31, 2018.

G&A expenses were $2.8 million for the three months ended March 31, 2018, as compared to $1.9 million for the same period in 2017. The increase is primarily related to fees associated with the Strongbridge License Agreement.

Excluding the impact of foreign exchange rate fluctuations and the recording of transaction costs related to potential financing activities (not currently known or estimable), we expect that G&A expenses will range between $8.0 million and $10.0 million in 2018.

Selling expenses were $1.6 million for the three months ended March 31, 2018, as compared to $1.5 million for the same period in 2017. Most of the selling expenses for the three months ended March 31, 2018 were for the payment of fees for the execution of the Strongbridge License Agreement. For the three months ended March 31, 2017, the costs were for our sales force co-promotion activities as well as our sales management team. Based on currently available information, we expect selling expenses to range between $1.8 million and $2.1 million in 2018.

Net finance income was $1.9 million for the three months ended March 31, 2018, as compared to $1.5 million, for the same period in 2017. The increase in finance income is mainly attributable to the change in fair value of warrant liability. Such change in fair value results from the periodic "mark-to-market" revaluation, via the application of pricing models, of outstanding share purchase warrants. The closing price of our common shares, which, on the NASDAQ, fluctuated from $1.46 to $2.41 during the three months ended March 31, 2018, compared to $2.45 to $3.65 during the same period in 2017, also had a direct impact on the change in fair value of warrant liability.

Net income for the three months ended March 31, 2018 was $14.4 million (or $0.88 per share), as compared to a net loss of $4.1 million (or $0.31 per share) for the same period in 2017. The increase in net income for the three months ended March 31, 2018 is a result of the revenue recognition of the $24.0 million upfront payment received for the Strongbridge License Agreement.

Liquidity, Cash Flows and Capital Resources

At March 31, 2018, we had $24.5 million of cash and cash equivalents. We expect existing cash balances and operating cash flows will provide us with adequate funds to support our current operating plan for at least the next twelve months and for the foreseeable future.

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Condensed Interim Consolidated Statements of Financial Position

(Unaudited)	March 31, 2018	December 31, 2017
	$	$
ASSETS		
Current Assets		
Cash and cash equivalents	**24,548**	7,780
Trade and other receivables	**304**	221
Inventory	**1,096**	643
Prepaid expenses and other current assets	**912**	737
Total current assets	**26,860**	9,381
Restricted cash equivalents	**388**	381
Property, plant and equipment	**94**	101
Identifiable intangible assets	**104**	90
Other non-current assets	**151**	150
Deferred tax asset	**—**	3,479
Goodwill	**8,844**	8,613
Total assets	**36,441**	22,195
LIABILITIES		
Current liabilities		
Payables and accrued liabilities	**3,144**	2,987
Provision for restructuring costs	**864**	2,296
Income taxes payable	**3,300**	**—**
Current portion of deferred revenues	**—**	486
Total Current liabilities	**7,308**	5,769
Deferred revenues	**—**	55
Warrant liability	**2,069**	3,897
Employee future benefits	**14,569**	14,229
Provisions and other non-current liabilities	**953**	1,028
Total Liabilities	**24,899**	24,978
SHAREHOLDERS' EQUITY (DEFICIT)		
Share capital	**222,335**	222,335
Other capital	**88,895**	88,772
Deficit	**(299,737)**	(314,161)
Accumulated other comprehensive income	**49**	271
Total Shareholders' Equity (Deficiency)	**11,542**	(2,783)
Total Liabilities and Shareholders' Equity (Deficiency)	**36,441**	22,195

Commitments and contingencies

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Condensed Interim Consolidated Statements of Comprehensive Income (Loss) Information

(Unaudited) *(in thousands, except share and per share data)*	Three months ended March 31 2018	 2017
	$	$
Revenues		
Sales commission and other	**90**	153
Licensing revenue	**24,568**	108
Total revenues	**24,658**	261
Operating expenses		
Research and development costs	**833**	2,455
General and administrative expenses	**2,786**	1,881
Selling expenses	**1,641**	1,542
Total operating expenses	**5,260**	5,878
Income (loss) from operations	**19,398**	(5,617)
Gain due to changes in foreign currency exchange rates	**48**	65
Change in fair value of warrant liability	**1,828**	1,403
Other finance income	**18**	18
Net finance income	**1,894**	1,486
Income (loss) before income taxes	**21,292**	(4,131)
Income taxes	**(6,868)**	—
Net income (loss)	**14,424**	(4,131)
Other comprehensive Income (loss):		
Items that may be reclassified subsequently to profit or loss:		
Foreign currency translation adjustments	**(222)**	(133)
Items that will not be reclassified to profit or loss:		
Actuarial gain on defined benefit plans	**—**	441
Comprehensive income (loss)	**14,202**	(3,823)
Net income (loss) per share (basic)	**0.88**	(0.31)
Net income (loss) per share (diluted)	**0.87**	(0.31)
Weighted average number of shares outstanding:		
Basic	**16,440,760**	13,175,866
Diluted	**16,493,363**	13,175,866

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Conference Call

The Company will host a conference call to discuss these results on Tuesday, May 8, 2018, at 8:30 a.m., Eastern Time. Participants may access the conference call by telephone using the following dial-in numbers:

- Toll-Free: 877-407-8029, Confirmation #13679691
- Toll: 201-689-8029, Confirmation #13679691

A replay of the conference call will also be available on the Company's website for a period of 30 days.
For reference, the Management's Discussion and Analysis of Financial Condition and Results of Operations for the first quarter 2018, as well as the Company's audited consolidated financial statements as at March 31, 2018, 2017, 2016 and 2015, can be found at www.zentaris.com in the "Investors" section.

About Aeterna Zentaris Inc.

Aeterna Zentaris Inc. (the "Company") is a specialty biopharmaceutical company focused on developing and commercializing, principally through out-licensing arrangements, Macrilen™ (macimorelin), an orally available ghrelin agonist, to be used in the diagnosis of patients with adult growth hormone deficiency (AGHD). On January 17, 2018, Aeterna Zentaris announced that that it had, through a wholly-owned subsidiary, entered into a license and assignment agreement with a wholly-owned subsidiary of Strongbridge Biopharma plc to carry out development, manufacturing, registration and commercialization of Macrilen™ (macimorelin) in the United States and Canada. On December 20, 2017 the Company announced that the U.S. Food and Drug Administration (FDA) granted marketing approval for Macrilen™ (macimorelin). On November 27, 2017 Aeterna Zentaris announced that the Marketing Authorization Application (MAA) for the use of Macrilen™ (macimorelin) for the evaluation of AGHD was accepted by the European Medicines Agency (EMA) for regulatory review. For more information, visit www.zentaris.com.

Forward-Looking Statements

This press release contains forward-looking statements made pursuant to the safe-harbor provisions of the U.S. Securities Litigation Reform Act of 1995 and applicable Canadian securities laws, 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 risks and uncertainties, many of which are discussed under the caption "Key Information - Risk Factors" in our most recent Annual Report on Form 20-F filed with the relevant Canadian securities regulatory authorities in lieu of an annual information form and with the U.S. Securities and Exchange Commission ("SEC"). Such risks and uncertainties include, among others, 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 launch the product, 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 our product candidates, 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, the ability of Aeterna Zentaris 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 products, the impact of securities class action litigation, the litigation involving two former officers of Aeterna Zentaris, or other litigation, on our cash flow, results of operations and financial position; any evaluation of potential strategic alternatives to maximize potential future growth and stakeholder value may not result in any such alternative being pursued, and even if pursued, may not result in the anticipated benefits, 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 the quarterly and annual filings of Aeterna Zentaris with the applicable Canadian securities regulators and the SEC 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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