Aeterna Zentaris Inc. Form 20-F

March 28, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

"Registration Statement Pursuant to Section 12(b) or 12(g) of The Securities Exchange Act of 1934

Annual Report Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934 for the fiscal year ended \circ December 31, 2017

OR

"Transition Report Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

"Shell Company Report Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934 Commission file number 0-30752

AETERNA ZENTARIS INC.

(Exact Name of Registrant as Specified in its Charter)

Not Applicable

(Translation of Registrant's Name into English)

Canada

(Jurisdiction of Incorporation)

315 Sigma Drive

Summerville, South Carolina, USA

29486

(Address of Principal Executive Offices)

Michael V. Ward

Telephone: 843-900-3201 E-mail: mward@aezsinc.com

315 Sigma Drive

Summerville, South Carolina

29486

(Name, Telephone, E-mail and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:
Title of Each Class

Name of Each Exchange on Which Registered

Common Shares

NASDAQ Capital Market
Toronto Stock Exchange

Securities registered or to be registered pursuant to Section 12(g) of the Act: NONE

Securities for which there is a reporting obligation pursuant to Section 15(d) of the ACT: NONE

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as at the close of the period covered by the annual report: 16,440,760 Common Shares as at December 31, 2017.

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes "No ý

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes "No ý

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No "

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No "

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definitions of "accelerated filer," "large accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer "Accelerated filer "Non-accelerated filer ý Emerging growth company "
If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrent has elected not to use the extended transition period for complying with any new or

check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act.

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

US GAAP "International Financial Reporting Standards as issued by the Other "International Accounting Standards Board ý

If "other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. Item $17\,^{\circ}$ Item $18\,^{\circ}$

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes " No \circ

Basis of Presentation

General

Except where the context otherwise requires, all references in this Annual Report on Form 20-F to the "Company", "Aeterna Zentaris", "we", "us", "our" or similar words or phrases are to Aeterna Zentaris Inc. and its subsidiaries, taken together. In this Annual Report on Form 20-F, references to "\$" and "U.S.\$" are to United States ("U.S.") dollars, references to "CAN\$" are to Canadian dollars and references to "EUR" are to euros. Unless otherwise indicated, the statistical and financial data contained in this Annual Report on Form 20-F are presented as at December 31, 2017.

All share, option and share purchase warrant as well as per share, option and share purchase warrant information presented in this Annual Report on Form 20-F have been adjusted, including proportionate adjustments being made to each option and share purchase warrant exercise price, to reflect and to give effect to a share consolidation (or reverse stock split), on November 17, 2015, of our issued and outstanding common shares on a 100-to-1 basis (the "Share Consolidation"). The Share Consolidation affected all shareholders, optionholders and warrantholders uniformly and thus did not materially affect any securityholder's percentage of ownership interest.

This Annual Report on Form 20-F also contains certain information regarding products or product candidates that may potentially compete with our products and product candidates, and such information has been primarily derived from information made publicly available by the companies developing such potentially competing products and product candidates and has not been independently verified by Aeterna Zentaris Inc.

Forward-Looking Statements

This Annual Report on Form 20-F contains forward-looking statements 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 risks and uncertainties, including those discussed in this 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 ("SEC"). 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 now heavy dependence on the success of MacrillenTM (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 the Company to efficiently commercialize or out-license MacrilenTM (macimorelin), the degree of market acceptance of MacrilenTM (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 of our former officers, 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 Company's 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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PART I

Item 1. Identity of Directors, Senior Management and Advisers

A. Directors and senior management

Not applicable.

B. Advisers

Not applicable.

C. Auditors

Not applicable.

Item 2. Offer Statistics and Expected Timetable

A. Offer statistics

Not applicable.

B. Method and expected timetable

Not applicable.

Item 3. Key Information

A. Selected financial data

The consolidated statement of comprehensive (loss) income information set forth in this Item 3.A. with respect to the years ended December 31, 2017, 2016 and 2015 and the consolidated statement of financial position information as at December 31, 2017 and 2016 have been derived from the audited consolidated financial statements set forth in Item 18, which have been prepared in accordance with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB"). The consolidated statement of comprehensive (loss) income information with respect to the years ended December 31, 2014 and 2013 and the consolidated statement of financial position information as at December 31, 2015, 2014 and 2013 set forth in this Item 3.A. have been derived from our previous consolidated financial statements not included herein, and have also been prepared in accordance with IFRS, as issued by the IASB. The selected financial data should be read in conjunction with our audited consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 20-F, as well as "Item 5. – Operating and Financial Review and Prospects" of this Annual Report on Form 20-F.

The Company has not declared or paid any dividends per share during the periods covered by the selected financial data.

1

Consolidated Statements of Comprehensive (Loss) Income Information

(in thousands of U.S. dollars, except share and per share data)

Derived from consolidated financial statements prepared in accordance with IFRS, as issued by the IASB

December 31,

20172016 2015 2014 2013 \$ \$ \$ \$ \$

Revenues

Sales commission and other 465 414 297 — 96

License fees 458 497 248 11