UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2018

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number: 001-35112

Aevi Genomic Medicine, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**98-0217544**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
435 Devon Park Drive, Suite 715 Wayne, Pennsylvania	**19087**
(Address of Principal Executive Offices)	**(Zip Code)**

(610) 254-4201
(Registrant's telephone number, including area code)

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

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 ☒ 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 ☒ No ☐

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

Large accelerated filer	☐		Accelerated filer	☐
Non-accelerated filer	☐	(Do not check if a smaller reporting company)	Smaller reporting company	☒
Emerging growth company	☐			

If an emerging growth company, indicate by 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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of May 10, 2018, the registrant had 59,337,265 shares of common stock, $0.0001 par value, outstanding.

AEVI GENOMIC MEDICINE, INC.
FORM 10-Q
TABLE OF CONTENTS

Unless the context otherwise requires, all references in this Quarterly Report on Form 10-Q to the "Company," "Aevi Genomic Medicine," "we," "us" and "our" refer to Aevi Genomic Medicine, Inc., a Delaware corporation organized on January 27, 2000, and its wholly-owned subsidiaries, Medgenics Medical (Israel) Ltd. and neuroFix, LLC. We use the Aevi Genomic Medicine logo as a trademark in the United States and elsewhere. All other trademarks or trade names referred to in this document are the property of their respective owners.

AEVI GENOMIC MEDICINE, INC. AND ITS SUBSIDIARY

PART I - FINANCIAL INFORMATION

ITEM 1. Financial Statements

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)

	March 31, 2018 Unaudited	December 31, 2017 Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 26,520	$ 33,729
Prepaid expenses and other current assets	801	893
Total current assets	27,321	34,622
LONG-TERM ASSETS:		
Lease deposits	11	11
Property and equipment, net	69	85
Other long-term assets	33	43
Total long-term assets	113	139
Total assets	$ 27,434	$ 34,761
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 1,685	$ 943
Other accounts payable and accrued expenses	3,054	3,197
Total current liabilities	4,739	4,140
Total liabilities	4,739	4,140
STOCKHOLDERS' EQUITY:		
Common stock - $0.0001 par value; 200,000,000 shares authorized; 59,337,265 shares issued and outstanding at March 31, 2018; 59,332,265 shares issued and outstanding at December 31, 2017	$ 6	$ 6
Additional paid-in capital	246,376	245,593
Accumulated deficit	(223,687)	(214,978)
Total stockholders' equity	22,695	30,621
Total liabilities and stockholders' equity	$ 27,434	$ 34,761

The accompanying notes are an integral part of the condensed consolidated financial statements.

AEVI GENOMIC MEDICINE, INC. AND ITS SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)

	Three months ended March 31,	
	2018	2017
	Unaudited	
Research and development expenses	$ 6,561	$ 7,947
General and administrative expenses	2,174	2,988
Operating loss	(8,735)	(10,935)
Financial income	26	18
Net loss	$ (8,709)	$ (10,917)
Basic and diluted loss per share	$ (0.15)	$ (0.29)
Weighted average number of common stock used in computing basic and diluted loss per share	59,334,821	37,108,261

The accompanying notes are an integral part of the condensed consolidated financial statements.

AEVI GENOMIC MEDICINE, INC. AND ITS SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Three months ended March 31,	
	2018	**2017**
	Unaudited	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (8,709)	$ (10,917)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation	16	41
Stock-based compensation	749	1,001
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	92	(646)
Trade payables	742	2,663
Other accounts payable and accrued expenses	(143)	(2,796)
Other long term assets	10	-
Net cash used in operating activities	$ (7,243)	$ (10,654)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	-	-
Net cash provided by (used in) investing activities	$ -	$ -
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of options and warrants	34	19
Net cash provided by financing activities	$ 34	$ 19
Decrease in cash and cash equivalents	(7,209)	(10,635)
Balance of cash and cash equivalents at the beginning of the period	33,729	39,838
Balance of cash and cash equivalents at the end of the period	$ 26,520	$ 29,203

The accompanying notes are an integral part of the condensed consolidated financial statements.

AEVI GENOMIC MEDICINE, INC. AND ITS SUBSIDIARY

NOTES TO THE FINANCIAL STATEMENTS
(In thousands, except share and per share data)

NOTE 1: GENERAL

a. Aevi Genomic Medicine Inc. (the "Company") was incorporated in January 2000 in Delaware as Medgenics, Inc. The Company has a wholly-owned subsidiary, Medgenics Medical Israel Ltd. (the "Subsidiary"), which was incorporated in Israel in March 2000. The Company is a clinical stage biopharmaceutical company with an emphasis on genomic medicine.

Since October 21, 2016 the Company's common stock (the "Common Stock") has been traded on the NASDAQ Global Market.

b. As reflected in the accompanying financial statements, the Company incurred a net loss and negative cash flow from operating activities for the three-month period ended March 31, 2018 of $8,709 and $7,243, respectively. The accumulated deficit as of March 31, 2018 was $223,687. As of March 31, 2018, the Company had cash and cash equivalents of $26,520, which it believes will provide funding for its operations into the first quarter of 2019. The Company and the Subsidiary have not yet generated revenues from product sales. See Note 3 below, for additional information regarding liquidity risks and management's plans.

c. The Children's Hospital of Philadelphia Foundation (the "CHOP Foundation") is our largest stockholder. As of March 31, 2018, the CHOP Foundation beneficially owned 18,697,233 shares of our common stock. The shares of common stock beneficially owned by the CHOP Foundation represent approximately 30.1% of our outstanding shares of common stock.

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES

a. The accompanying unaudited condensed financial statements of the Company, have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and the rules of the Securities and Exchange Commission ("SEC") and should be read in conjunction with the audited financial statements and notes thereto included in the Annual Report on Form 10-K for the year ended December 31, 2017 ("2017 Form 10-K") as filed with the SEC. In the opinion of management, all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of financial position and the results of operations for the interim periods presented have been reflected herein. The results of operations for interim periods are not necessarily indicative of the results to be expected for the full year. Notes to the financial statements that would substantially duplicate the disclosure contained in the audited financial statements for the most recent fiscal year as reported in the 2017 Form 10-K have been omitted.

b. Recently issued accounting pronouncements:

In 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which will establish the principles that lessees and lessors shall apply to report useful information to users of financial statements about the amount, timing, and uncertainty of cash flows arising from a lease. The pronouncement is effective for fiscal years beginning after December 15, 2018. The Company is currently evaluating the effect this guidance will have on the Company's consolidated financial statements.

In 2016, the FASB issued ASU 2016-09, Compensation-Stock Compensation (Topic 718), Improvements to Employee Share-Based Payment Accounting, which is meant to reduce complexity involving several aspects of the accounting for employee share-based payment transactions, including the income tax consequences, classifications of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 became effective for the Company in the first quarter of 2017 and was applied using a modified retrospective transition approach. Under ASU 2016-09 the Company has elected to no longer estimate forfeiture rates in determining its stock compensation expense and will true up forfeitures as they occur. As a result of the adoption, the Company recorded a cumulative adjustment to accumulated deficit as of December 31, 2016 for $230.

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company's consolidated financial statements upon adoption.

NOTE 3: LIQUIDITY RISKS AND MANAGEMENT'S PLANS

The future success of the Company is dependent on its ability to develop its product candidates and ultimately upon its ability to attain profitable operations. The Company is subject to a number of risks similar to other early-stage life science companies, including, but not limited to, successful discovery and development of its product candidates, raising additional capital with favorable terms, development by its competitors of new technological innovations, protection of proprietary technology and market acceptance of the Company's products. The successful discovery and development of product candidates requires substantial working capital which may not be available to the Company on favorable terms.

The Company has financed its operations primarily through issuance of equity and grants from other third parties. As of March 31, 2018, the Company had cash and cash equivalents of $26,520 and liabilities of $4,739. The Company has incurred recurring operating losses since inception. For the three months ended March 31, 2018, the Company incurred a net loss of $8,709 and as of March 31, 2018 the Company has an accumulated deficit of $223,687. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of its product candidates and its preclinical programs, and its administrative organization. The Company will require substantial additional financing to fund its operations and to continue to execute its strategy. These conditions raise substantial doubt about its ability to continue as a going concern within one year after the date that the financial statements are issued.

To alleviate the conditions that raise substantial doubt about the Company's ability to continue as a going concern, management is exploring various sources of funding such as strategic collaborations, license agreements, and issuance of equity and/or debt securities. If the Company raises additional funds through strategic collaborations and alliances or licensing agreements with third parties, which may include existing collaboration partners, the Company may have to relinquish valuable rights to its technologies or product candidates, including AEVI-001 and AEVI-002, or grant licenses on terms that are not favorable to the Company. To the extent that the Company raises additional capital through the sale of equity, the ownership interest of its existing shareholders will be diluted and other preferences may be necessary that adversely affect the rights of existing shareholders. If none of these alternatives is available, or if available, the Company is unable to raise sufficient capital through such transactions, it will not have sufficient cash resources and liquidity to fund its business operations for at least the next year after the date of the filing of this Quarterly Report on Form 10-Q. Accordingly, management has concluded that substantial doubt exists with respect to the Company's ability to continue as a going concern within one year after the date of the filing of this Quarterly Report on Form 10-Q.

NOTE 4: COMMITMENTS AND CONTINGENCIES

In November 2014, the Company entered into a research agreement with the Children's Hospital of Philadelphia ("CHOP"). Under the terms of the agreement, the Company agreed to sponsor research at CHOP with respect to the recruitment and genetic analysis of patients with rare diseases to accelerate discovery of diagnostic and therapeutic targets.

CHOP granted the Company options over certain intellectual property created in the course of the research. The initial term of the Research Agreement was one year. The Company had the unilateral right to extend the term of the Research Agreement for an additional two-year term beyond the initial term and to provide additional funding for such an extension.

In June 2017, the Company entered into an amendment to the Research Agreement, which extended the Research Agreement through June 30, 2019, for which payments totaling $5,937 will be due in 2018 and $2,375 will be due in 2019. As of March 31, 2018, the Company has total payables related to the CHOP sponsored research agreement of $1,389, allocated between accrued expenses and trade payables.

NOTE 5:- STOCKHOLDERS' EQUITY

a. Issuance of stock options and warrants to employees and directors:

A summary of the Company's activity for options and warrants granted to employees and directors is as follows:

	Three months ended March 31, 2018			
	Number of options and warrants	Weighted average exercise price	Weighted average remaining contractual terms (years)	Aggregate intrinsic value
Outstanding at December 31, 2017	11,110,362	$ 4.34	6.43	$ 1
Granted	15,000	$ 1.52		
Exercised	-	$ -		
Forfeited	(1,684,264)	$ 4.50		
Outstanding at March 31, 2018	9,441,098	$ 4.31	6.91	$ 1,448
Vested and expected to vest at March 31, 2018	9,259,798	$ 4.37	6.85	$ 1,322
Exercisable at March 31, 2018	6,017,740	$ 5.16	5.75	$ 5

As of March 31, 2018, there was $3,995 of total unrecognized compensation cost related to non-vested stock-based compensation arrangements granted to employees and directors. That cost is expected to be recognized over a weighted-average period of 1.65 years.

b. Issuance of options and warrants to consultants:

A summary of the Company's activity for warrants and options granted to consultants is as follows:

	Three months ended March 31, 2018			
	Number of options and warrants	Weighted average exercise price	Weighted average remaining contractual terms (years)	Aggregate intrinsic value
Outstanding at December 31, 2017	160,000	$ 3.62	2.45	$ -
Granted	40,000	$ 1.52		
Exercised	-	$ -		
Forfeited	(23,300)	$ 1.40		
Outstanding at March 31, 2018	176,700	$ 3.44	2.93	$ 25
Vested and expected to vest at March 31, 2018	161,000	$ 3.66	2.27	$ 13
Exercisable at March 31, 2018	161,000	$ 3.66	2.27	$ 13

As of March 31, 2018, there was no unrecognized compensation cost related to non-vested stock-based compensation arrangements granted to consultants.

c. Stock-based compensation expense:

Compensation expense related to warrants and options granted to employees, directors and consultants was recorded in the Consolidated Statement of Operations in the following line items:

	Three months ended March 31,	
	2018	2017
Research and development expenses	$ 332	$ 445
General and administrative expenses	417	556
	$ 749	$ 1,001

d. Summary of shares to be issued upon exercise of options and warrants:

A summary of shares to be issued upon exercise of all the options and warrants, segregated into ranges, as of March 31, 2018 is presented in the following table:

		As of March 31, 2018		
Options / Warrants	**Exercise price per share ($)**	**Shares to be issued upon exercise of options and warrants outstanding**	**Shares to be issued upon exercise of options and warrants exercisable**	**Weighted average remaining contractual terms of options and warrants (in years)**
Options:				
Granted to employees and directors				
	1.07-2.66	2,130,050	69,750	9.2
	3.14-5.07	4,657,567	3,456,967	6.8
	5.22-8.80	2,512,271	2,349,813	5.3
		9,299,888	5,876,530	
Granted to consultants				
	1.23-1.52	41,700	26,000	9.8
	4.82	10,000	10,000	8.6
		51,700	36,000	
Total shares to be issued upon exercise of options		9,351,588	5,912,530	
Warrants:				
Issued to employees and directors	2.84	141,210	141,210	4.6
Issued to consultants	3.76-4.99	125,000	125,000	0.2
Issued to investors	2.84	3,812,694	3,812,694	4.6
Total shares to be issued upon exercise of warrants		4,078,904	4,078,904	
Total shares to be issued upon exercise of options and warrants		13,430,492	9,991,434	

NOTE 6: LOSS PER SHARE

The Company computes basic net loss per share by dividing net loss by the weighted average number of shares outstanding, which includes stock issued and outstanding. The Company computes diluted net loss per share by dividing net loss by the weighted average number of shares and potential shares from outstanding stock options. Since the Company had a net loss for all periods presented, the effect of all potentially dilutive securities is anti-dilutive.

The following table presents anti-dilutive shares for the three months ended March 31, 2018 and 2017:

	Three months ended March 31,	
	2018	**2017**
Weighted-average anti-dilutive shares related to:		
Outstanding stock options	10,278,652	10,767,160
Outstanding warrants	5,606,349	4,909,393
	15,885,001	15,676,553

NOTE 7: SUBSEQUENT EVENTS

The Company became aware that certain option grants in August 2017 to Michael Cola, Garry Neil and Brian Piper exceeded the applicable annual limit set forth in the Company's incentive compensation plan and were, therefore, null and void. Each applicable executive has acknowledged the cancellation of the excess portion of such awards to reduce the number of options granted to meet the plan limitation. Given the recent changes in U.S. tax law, this annual limitation is no longer in effect. In order to provide the same relative value of such awards, the Company's Compensation Committee and Board, on May 14, 2018, approved the grant of options to purchase an aggregate of 1,020,000 shares to the executives (450,000 shares in the case of Mr. Cola, 300,000 shares in the case of Dr. Neil and 270,000 shares in the case of Mr. Piper) at an exercise price of $1.51, the closing price of the Company's common stock on the date of grant. The expense recognized in the financial statements for the awards which were cancelled was not material to the consolidated financial statements.

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. The statements contained in this Quarterly Report on Form 10-Q that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements are often identified by the use of words such as, but not limited to, "can," "may," "will," "should," "could," "would," "expects," "plans," "continues," "anticipates," "intends," "seeks," "targets," "believes," "estimates," "projects," "predicts," "potential" and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to them. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2017, and any updates to those risk factors included in Part II, Item 1A of this Quarterly Report on Form 10-Q. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

We are a clinical stage biopharmaceutical company with an emphasis on identifying the genetic drivers of disease and applying this understanding to the pursuit of differentiated novel therapies primarily for pediatric onset, life-altering diseases, including rare and orphan diseases. We look to find treatments for genetically defined diseases for which there are limited therapeutic options currently available, with a primary focus on pediatric patients. This strategy begins with identifying and genetically validating a therapeutic target and using genomics to guide product development. The strategy also involves identifying and acquiring otherwise abandoned or overlooked drug candidates and matching targets and mechanisms of action to novel genetic discoveries.

We have partnered with the Center for Applied Genomics, or CAG, at The Children's Hospital of Philadelphia, or CHOP, to implement a genomic medicine driven approach to drug development. Included in the assets at CAG is a fully automated biorepository containing specimens from more than 75,000 pediatric patients and 150,000 relatives of those patients. The sample is highly enriched for rare and orphan diseases and the large majority of patients have been genotyped. Their phenotypes are recorded in a modern electronic health record that is linked to the genomics database and biorepository. The patients in the database have consented to anonymized use of their data for research and follow up contact if needed.

CAG continues to discover important and novel genetic biomarkers by both genome-wide association studies and exome sequencing and analysis of affected individuals and their family members. Such markers not only identify patients with the disease but frequently point to the potential cause of the disease and suggest targets and feasible intervention strategies that include protein or peptide therapy, monoclonal antibodies, drugs or gene therapy. By working initially in pediatric populations of specific diseases, we can try to minimize the confounding environmental factors seen in older patients. In addition, the availability of robust genetic biomarkers allows us to design trials that focus on a highly-enriched patient population that we believe is more likely to respond to targeted therapies and further enhance the likelihood of clinical and regulatory success. We believe this will allow us to implement clinical development programs that will lead to medicines that can address critical needs in patients suffering from rare and orphan diseases.

The Children's Hospital of Philadelphia Foundation (the "CHOP Foundation") is our largest stockholder. As of March 31, 2018, the CHOP Foundation beneficially owned 18,697,233 shares of our common stock. The shares of common stock beneficially owned by the CHOP Foundation represent approximately 30.1% of our outstanding shares of common stock.

AEVI-001 (mGluR+ Genetic Subset Attention Deficit Hyperactivity Disorder ("ADHD")

The lead program from our genomic research collaboration with CHOP is the development candidate AEVI-001, an oral, non-stimulant glutamatergic neuromodulator. Through our acquisition of neuroFix, LLC, or neuroFix, in September 2015, we acquired the rights to develop AEVI-001 (then known as NFC-1), as well as the rights to certain data derived from a clinical trial and other studies of AEVI-001.

The selection of AEVI-001 for development in the mGluR+ ADHD patients was the result of a rational search process conducted to specifically identify therapeutic candidates with a demonstrated ability to modulate glutamate signaling via the mGluR network. The role of glutamate in ADHD and other central nervous system ("CNS") disorders is supported by recent neuroimaging studies that suggest glutamate levels are abnormal in children with ADHD. These abnormalities appear to be concentrated in the anterior singular cortex region of the brain, as evidenced by volumetric and functional magnetic resonance imagery studies, as well as targeted studies of magnetic resonance spectroscopy. Additional supportive evidence for targeting glutamate modulation is provided by genetic studies that have identified mutations in glutamatergic genes that are enriched in children with ADHD.

Our ADHD Opportunity

We are developing AEVI-001 to treat a sub-population of ADHD patients who have genetic mutations that disrupt the mGluR network, resulting in glutamate imbalance. ADHD is one of the most common childhood neurodevelopmental disorders. In the United States, the Centers for Disease Control estimates that 6.4 million children 4-17 years of age (11%) have been diagnosed with ADHD. It is usually first diagnosed in childhood and often lasts into adulthood. Approximately 22% of ADHD patients aged 6-17 years are mGluR mutation positive, thereby representing approximately 1.5 million pediatric patients in the United States, and assuming a similar prevalence rate in adults, potentially representing 2.5 million adult patients in the United States.

ADHD is defined as a persistent pattern of inattention and/or hyperactivity-impulsivity that interferes with functioning or development. ADHD can cause significant impairment in childhood and throughout the lifespan, as well as increased mortality and psychosocial adversity. There is no definitive management for ADHD; current management frequently includes a combination of educational support, behavioral interventions, and pharmacotherapy. Current standard of care is the stimulant class of medications including immediate- and extended-release methylphenidate and amphetamine; these products represent 90% of sales in the United States. In 2016, ADHD pharmaceutical product sales in the United States were approximately $11 billion, and grew at a compounded annual growth rate of approximately 2% from 2012 to 2016. However, while conferring great benefit for many individuals, currently available ADHD medications also have significant adverse effects including decreased appetite, weight loss, and insomnia.

Prevalence of mGluR Network Mutations

To examine the prevalence of mGluR network mutations in the broader pediatric and adolescent ADHD populations, we conducted a non-interventional phenotype/genotype study at 32 sites across the United States. The study genotyped 1,876 ADHD patients aged 6-17 years, with 420 children and adolescents being mGluR+ (22.4%). A higher prevalence (75/292, 26%) was seen in patients aged 6-12 years than patients aged 13-17 years (344/1584, 21%). The data also showed that patients with the mGluR mutations had statistically significantly higher prevalence of symptoms associated with inappropriate movements, disruptive behavior, and anger control.

mGluR Network Mutations Highly Predictive of ADHD

A study identified 3,445 ADHD patients from the CHOP Psychiatry and Behavioral Sciences Clinics, who had previously been genotyped, to classify the prevalence of copy number variation mGluR+ mutations and the proportion of those patients who had already been diagnosed with ADHD. The research demonstrated an association between mutations in the mGluR pathway and ADHD in pediatric patients who possess these mutations. The study also demonstrated the highly predictive capabilities of the genetic biomarker, as demonstrated by the fact that 98% of the patients with the identified mGluR network mutations had a positive diagnosis of ADHD (the study was conducted on a blinded basis). We believe the genomic validation for AEVI-001 could address a key inefficiency in the current ADHD diagnosis and treatment paradigm and may potentially lead to improved safety and ultimately a personalized approach to treatment.

Development of AEVI-001 in mGluR+ Genetic Subset ADHD

AEVI-001 completed a Phase 2/3 trial (which we refer to as the SAGA trial) in adolescent ADHD patients with specific mutations in their mGluR gene network, which we refer to as mGluR+ ADHD, in the first quarter of 2017. Although AEVI-001 did not meet the primary endpoint of reduction on the ADHD rating scale (ADHD-RS) compared to placebo, in the SAGA trial, the drug did demonstrate statistically significant and clinically meaningful improvement compared to placebo in a pre-specified responder analysis of improvement in ADHD-RS scores of 30% or more from baseline [ADHD-RS reduction of 17.6, $p < .005$]. In a second pre-specified responder analysis of Clinical Global Impression of Improvement scale (CGI-I), a key secondary endpoint, AEVI-001 demonstrated a statistically significant and clinically meaningful improvement compared to placebo [57% of patients treated with AEVI-001 achieved a score of much improved or very much improved compared to 33% on placebo, $p=0.0155$]. Additionally, the safety analysis demonstrated that AEVI-001 was well tolerated at all doses and the majority of adverse events were generally mild to moderate in severity. There were no serious adverse events.

Subsequent analysis of responder data from a subset of genomically identified patients in the SAGA trial identified nine genes (genetic subset) that appear to be predictive of clinically meaningful and statistically significant response on the ADHD-RS scales and CGI-I scales. These genes include certain glutamate metabotropic receptors and neurodevelopmental genes that are found in approximately 10% of pediatric ADHD patients.

One of the neurodevelopmental genes, contactin-4 (CNTN4), has been previously identified as being important in Autism Spectrum Disorder (ASD) and represents approximately 5% of the overall pediatric ADHD patient population. The CNTN4 mutation phenotype is relatively severe, with an increased prevalence of emotional dysregulation, which includes issues related to anger control, risk taking, and inappropriate movements and sounds. All of the CNTN4 mutation positive (CNTN4+) patients on treatment (n=6, 100%) had clinically meaningful and statistically significant response to therapy with AEVI-001 [ADHD-RS reduction of 20.8, p=0.03].

Importantly, these results clarify a path forward for the continued development of AEVI-001 in ADHD, as well as potentially in other neurodevelopmental disorders, including but not limited to ASD and Pediatric Generalized Anxiety Disorder. We have initiated a Phase 2 trial in the mGluR mutation positive genetic subset ADHD ("mGluR+ Genetic Subset ADHD") to confirm genetic responders to AEVI-001. Patient screening began in the third quarter of 2017 and data is expected by mid-2018.

In the United States, mGluR+ Genetic Subset ADHD represents approximately 10% of pediatric ADHD patients, estimated at 600,000 pediatric patients and, assuming a similar prevalence rate in adults, 1.5 million adult patients. Based on pricing assumptions of currently available ADHD therapies, as well as established compliance and adherence rates, this equates to a potential $2 billion to $3 billion market opportunity for AEVI-001.

Diagnostic Development in ADHD

As part of our precision medicine strategy, Aevi is looking to develop and commercialize novel diagnostic tests to support therapies in development. For AEVI-001, Aevi is developing a stand-alone diagnostic to be used as an aid in the diagnosis of ADHD in patients aged 6-17, based on the discovery that mutations in the mGluR network are highly associated with ADHD. Aevi has engaged in discussions with the US FDA on seeking a path to approval for the diagnostic test, although there is no guarantee that the test will be approved. In addition to potentially providing valuable information for the diagnosis of pediatric patients with mGluR+ ADHD, the diagnostic could support pre-identification of patients for future clinical trials in ADHD.

Previous Study of AEVI-001

The originator company for AEVI-001, Nippon Shinyaku, conducted research showing the ability of AEVI-001 to cross the blood-brain barrier and ameliorate cognitive impairment in animal behavioral models, at concentrations achievable in humans. AEVI-001 was shown to have a compelling pharmacokinetic and metabolic profile and to be a pan-selective activator and modulator of multiple mGluRs. Nippon Shinyaku studied AEVI-001 in vascular dementia, where approximately 1,000 adult patients were exposed to AEVI-001 for periods up to 12 months, in a development program that progressed to Phase 3. AEVI-001 was shown to be well tolerated with no treatment-emergent serious adverse events in this patient population, but was not effective for the treatment of vascular dementia.

The GREAT Study

A Phase Ib proof-of-concept trial (which we refer to as the GREAT trial) of AEVI-001 in adolescent patients with ADHD was completed in 2015. The study enrolled 30 adolescents aged 12-17 with severe and genetically confirmed mGluR+ ADHD. Of the 30 enrolled patients, 17 had Tier 1 mGluR mutations, which are mutations in genes in the mGluR receptors or in genes that directly influence mGluR signaling. Seven patients had Tier 2 mutations, which are mutations in genes that encode proteins that influence mGluR. The remaining six patients had more distal Tier 3 mutations, which are mutations in genes that encode proteins that influence Tier 1 and Tier 2 genes.

Part 1 of the study measured safety and the pharmacokinetic profile of single ascending doses of 50-800mg of AEVI- 001. Part 2 of the study was single-blinded to patients and caregivers. Dosing was one week with placebo followed by four weeks of ascending doses from 50mg BID to 400mg BID of AEVI-001. The study used the Clinical Global Impression of Symptom Improvement (CGI-I) and the Vanderbilt Parent Rating Score (similar to the ADHD Rating Scale) to assess efficacy. Despite not being powered to show efficacy, the study demonstrated dose and duration-dependent improvements and response rates.

The treatment effect was more robust over time and at higher doses. AEVI-001 showed weekly improvements in mean CGI-I for all patients from 3.79 during week 1 on placebo (baseline), 3.13 during week 2 (50mg BID), 2.79 during week 3 (100mg BID), 2.79 during week 4 (200mg BID) and 2.21 during week 5 (400mg BID). AEVI-001 likewise showed weekly improvements in mean Vanderbilt scores for all patients from 29.1 during week 1 on placebo (baseline), 26.4 during week 2 (50mg BID), 24.0 during week 3 (100mg BID), 23.3 during week 4 (200mg BID) and 22.5 during week 5 (400mg BID).

The GREAT study also confirmed the previously observed pharmacokinetic profile of AEVI-001, showing the therapy to be well tolerated with no treatment-related serious adverse effects. Following the conclusion of the study, a majority of patients enrolled in an open label long-term safety study. Full data from the study was presented at the American Academy of Child and Adolescent Psychiatry meeting in October 2015.

Development of AEVI-001 in 22q Deletion Syndrome (22q DS)

We completed work on a signal-finding trial for the treatment of the psychiatric symptoms of 22q Deletion Syndrome (22q DS) in 2017. 22q DS is an orphan, severe autism spectrum disorder with significant co-morbidities. The disease has a prevalence of between 1:2000-1:4000, roughly equivalent with the more recognized Down's Syndrome. Enrolling patients into the signal-finding study was difficult, with only two patients enrolled by the time the study ended. Due to the limited enrollment, it was not feasible to meaningfully interpret the resulting data, and the program was terminated.

Future Development of AEVI-001 in ASD

We are exploring a development opportunity for AEVI-001 for the treatment of mGluR+ patients with ASD to better define the patient phenotype and intend to initiate work on a proof-of-concept study to begin in the second half of 2018. In 2012, 1 in 68 children were diagnosed with ASD in the United States, increasing from 1 in 150 in 2000. There is a high unmet need for pharmaceutical treatments for ASD as currently approved medications are indicated only for the symptoms of irritability in ASD patients. There are currently limited pharmacotherapy options available to treat ASD.

AEVI-002 (Anti-LIGHT Monoclonal Antibody)

The second program arising out of our genomic research collaboration with CHOP is the development candidate AEVI-002, a potential first-in-class anti-LIGHT monoclonal antibody, or the Antibody, being developed for use in Pediatric Onset Crohn's disease. Pediatric Onset Crohn's disease has a more aggressive phenotype at younger ages. The genomic rationale for the use of anti-LIGHT antibody in Crohn's disease was validated by CAG research showing the association to a loss of function mutation in decoy receptor 3 (DcR3).

In June 2016, we entered into a Clinical Development and Option Agreement, or the Development and Option Agreement, with Kyowa Hakko Kirin Co., Ltd., or KHK, pursuant to which we acquired certain rights with respect to the development and potential commercialization of the Antibody. Under the Development and Option Agreement, we received an exclusive option for exclusive rights to develop products containing the Antibody, or an Antibody Licensed Product, exclusive rights to commercialize Antibody Licensed Product in various countries and to conduct various development activities with respect to the Antibody Licensed Product, including the conduct of a signal finding study testing the Antibody in Severe Pediatric Onset Inflammatory Bowel Disease.

An 8-week Phase Ib proof-of-concept study has been initiated at CHOP with the goal of enrolling up to 12 patients with a Pediatric Onset Crohn's disease diagnosis with most patients being refractory to treatment with TNF-α inhibitors, with or without a DcR3 mutation. The endpoints of the trial will include endoscopic evaluation, Crohn's Disease Activity Index ratings and safety. Initial data from the proof-of-concept study is expected by year-end 2018, at which point we will make a determination on our option to license exclusive rights to the Antibody for further development. Active recruitment for the trial is underway, although the identification and recruitment of patients into the proof-of-concept study has been extremely challenging, and to date no patients have been enrolled. The ability to produce initial data by year-end 2018 is highly dependent on timely recruiting; thus, continued difficulties in recruitment could cause a delay in the delivery of initial data for the program. In an effort to address the recruitment challenges, we are currently working to initiate three additional trial sites for the program.

Financial Operations Overview

We have generated significant losses to date, and we expect to continue to generate losses as we progress towards the commercialization of our product candidates. We incurred net losses of approximately $8.71 million for the three-month period ended March 31, 2018. As of March 31, 2018, we had stockholders' equity of approximately $22.70 million. As of March 31, 2018, we had cash and cash equivalents of $26.52 million. We believe that cash on hand will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2019. We anticipate operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of our product candidates and preclinical programs, and our administrative organization. We will require substantial additional financing to fund our operations and to continue to execute our strategy. These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date of the filing of this Quarterly Report on Form 10-Q. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, management is exploring various sources of funding such as strategic collaborations, license arrangements, and issuance of equity and/or debt securities. If we raise additional funds through strategic collaborations and alliances or licensing agreements with third parties, which may include existing collaboration partners, we may have to relinquish valuable rights to our technologies or product candidates, including AEVI-001 and AEVI-002, or grant licenses on terms that are not favorable to us. To the extent that we raise additional capital through the sale of equity, the ownership interest of our existing shareholders will be diluted and other preferences may be necessary that adversely affect the rights of existing shareholders. If none of these alternatives is available, or if available, if we are unable to raise sufficient capital through such transactions, we will not have sufficient cash resources and liquidity to fund our business operations for at least the next year following the date of the filing of this Quarterly Report on Form 10-Q. Accordingly, management has concluded that substantial doubt exists with respect to our ability to continue as a going concern within one year after the date of the filing of this Quarterly Report on Form 10-Q.

Research and Development Expense

Research and development expense consists of: (i) internal costs associated with our development activities; (ii) payments we make to third party contract research organizations, contract manufacturers, clinical trial sites and consultants; (iii) technology and intellectual property license costs; (iv) manufacturing development costs; (v) personnel related expenses, including salaries, and other related costs, including stock-based compensation expense, for the personnel involved in product development; (vi) activities related to regulatory filings and the advancement of our product candidates through preclinical studies and clinical trials; and (vii) facilities and other allocated expenses, which include direct and allocated expenses for rent, facility maintenance, as well as laboratory and other supplies. All research and development costs are expensed as incurred.

Conducting a significant amount of development is central to our business model. Product candidates in later-stage clinical development generally have higher development costs than those in earlier stages of development, primarily due to the significantly increased size and duration of the clinical trials. Research and development expenses will likely increase as we advance the development of AEVI-001 and AEVI-002 and look to advance our earlier-stage research and development projects.

The process of conducting pre-clinical studies and clinical trials necessary to obtain regulatory approval is costly and time consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among others, the quality of the product candidate's early clinical data, investment in the program, competition, manufacturing capabilities and commercial viability. As a result of these uncertainties, together with the uncertainty associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine the duration and completion costs of current or future clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates. Development timelines, probability of success and development costs vary widely. We are concurrently focusing on the development and potential commercialization of AEVI-002 under the Development and Option Agreement with KHK, advancing the development of AEVI-001 and advancing our earlier-stage research and development projects.

Research and development expenses are shown net of participation by third parties.

General and Administrative Expense

General and administrative expense consists primarily of salaries and other related costs, including stock-based compensation expense, for persons serving as our directors and in our executive, finance and accounting functions. Other general and administrative expense includes facility-related costs not otherwise included in research and development expense and professional fees for legal services and accounting services.

Results of Operations for the Three Months Ended March 31, 2018 and 2017

Research and Development Expenses

Research and development expenses for the three months ended March 31, 2018 were $6.56 million, decreasing from $7.95 million for the same period in 2017 mainly related to decreasing clinical trial/development activities.

General and Administrative Expenses

General and administrative expenses for the three months ended March 31, 2018 were $2.17 million, decreasing from $2.99 million for the same period in 2017 primarily due to decreased costs following the closure of our operations in Israel.

Financial Income and Expenses

Financial income and expense for the three months ended March 31, 2018 and 2017 were de minimis.

Liquidity and Capital Resources

Sources of Liquidity

We have financed our operations primarily through issuance of equity and grants from other third parties.

Cash Flows

We had cash and cash equivalents of $26.52 million at March 31, 2018, compared to $33.73 million as of December 31, 2017. The decrease in cash during the three months ended March 31, 2018 was primarily related to the advancement of our AEVI-001 program.

Net cash used in operating activities of $7.24 million for the three months ended March 31, 2018 and $10.65 million for the three months ended March 31, 2017 primarily reflected our cash expenses for our operations.

Net cash provided by and used in investing activities for the three months ended March 31, 2018 and 2017 were de minimis.

Net cash provided by financing activities for the three months ended March 31, 2018 and 2017 were de minimis.

Funding Requirements

Our future capital requirements will depend on a number of factors, including our success in targeting rare and orphan disease candidates, the timing and outcome of clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the acquisition of licenses to new products or compounds, the status of competitive products, the availability of financing, and our success in developing markets for our product candidates.

We believe that cash on hand will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the first quarter 2019. We have based this estimate on assumptions that may prove to be wrong and we could use our available resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials.

We do not anticipate that we will generate revenue from the sale of products for several years or more given the uncertainty of drug development. In the absence of additional funding or adequate funding from licensing or commercialization agreements, we expect our continuing operating losses to result in decreases in our cash balances. Absent significant corporate collaboration and licensing arrangements, we will need to finance our future cash needs through additional public or private equity offerings or debt financings in 2018. We do not currently have any commitments for future external funding. We may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate, and we may decide to raise additional funds even before we need them if the conditions for raising capital are favorable. We may seek to encourage holders of our warrants to exercise, sell additional equity or debt securities or obtain a bank credit facility. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. If we are unable to successfully raise sufficient additional capital, through future financings or through strategic and collaborative arrangements, we will not have sufficient cash to fund additional clinical trials and future operations.

Our plans include seeking additional investments and commercial agreements to continue our operations. Concurrent with the filing of this Quarterly Report on Form 10-Q, we intend to enter into an Equity Distribution Agreement pursuant to which we may from time-to-time issue and sell shares of our common stock having an aggregate offering price of up to $20,000,000 in an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act (the "ATM Facility"). However, there is no assurance that we will be successful in our efforts to raise the necessary capital and/or reach such commercial agreements to continue our planned research and development activities.

We will require substantial additional financing to fund our operations and to continue to execute our strategy. These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date of the filing of this Quarterly Report on Form 10-Q. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates.

While our significant accounting policies are more fully described in Note 2 to our financial statements included elsewhere in this Quarterly Report on Form 10-Q, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

Stock-Based Compensation

We account for stock options granted to employees and directors according to the Accounting Standards Codification No. 718 (ASC 718) "Compensation – Stock Compensation." Under ASC 718, stock-based compensation cost is measured at grant date, based on the estimated fair value of the award, and is recognized as an expense over the requisite service period on a straight-line basis.

For the purpose of valuing options granted to our employees and directors during the three months ended March 31, 2018 and 2017, we used the Binomial options pricing model. To determine the risk-free interest rate, we utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the contractual life of our awards. We estimated the expected life of the options granted based on anticipated exercises in the future periods assuming the success of our business model as currently forecast. The expected dividend yield reflects our current and expected future policy for dividends on our common stock. The expected stock price volatility for our stock options was calculated by examining historical volatilities for publicly traded industry peers and blending in our historical volatility. We will continue to analyze the expected stock price volatility as more historical data for our common stock becomes available. After adoption of ASU 2016-09 in the first quarter of 2017, we recognize forfeitures as they occur.

Off-Balance Sheet Arrangements

CHOP License Agreement and Research Agreement

In November 2014, we entered into a license agreement, or the License Agreement, and a sponsored research agreement, or the Research Agreement, each with CHOP. Under the terms of the License Agreement, CHOP granted us (i) an exclusive, sublicensable license to use certain patent rights covering potential diagnostic and therapeutic targets, (ii) an exclusive, non-sublicensable license to use certain biospecimen and phenotypic data collected from patients with rare and orphan diseases and their family members or the Biobank. In February 2017, we amended the License Agreement. The amendment allows us to extend the period of our exclusive commercial access to the Biobank for rolling two year periods. The cost of each extension is $125,000 per year. In June 2017, we entered into an amendment to the Research Agreement, which extended the Research Agreement through June 30, 2019, for which additional payments totaling $5.94 million will be due in 2018 and $2.38 million will be due in 2019. The amendment also allows us to extend the Research Agreement for rolling two year periods in connection with the Company extending its exclusive commercial access to the Biobank under the License Agreement.

Development and Option Agreement, with Kyowa Hakko Kirin Co., Ltd. (KHK)

In June 2016, we entered into the Development and Option Agreement with KHK pursuant to which we acquired certain rights with respect to the development and potential commercialization of AEVI-002, the Antibody. If we exercise our option under the Development and Option Agreement, KHK has 60 days to select one of two development and commercialization structures as follows:

PLAN A: Co-Development/Co-Commercialization Arrangement

If KHK selects the co-development/co-commercialization arrangement (Plan A), we will have the exclusive right to develop, manufacture and commercialize the Antibody Licensed Products in the Field in the United States and Canada. We will also be responsible for development and regulatory approval of the first Antibody Licensed Product in the European Union and then transferring such regulatory approval to KHK or its designee. We will be responsible for the manufacture of the Antibody Licensed Products for use by the parties in clinical trials as well as for commercialization in their respective fields and/or territories, with KHK purchasing the Antibody Licensed Products from us.

We will be required to pay KHK an initial license fee in the low single-digit millions of dollars upon the co-development/co-commercialization arrangement becoming effective. We may pay KHK up to an additional $18 million upon the achievement of certain regulatory milestones related to the Antibody Licensed Products. The parties will share the anticipated costs of development of the first Antibody Licensed Product in the Field in the United States, Canada and the European Union with us being responsible for any costs in excess of an agreed cap. The parties will split profits from our sales of Antibody Licensed Products in the United States and Canada equally. KHK will pay us low double-digit royalties for sales of Antibody Licensed Products outside the United States and Canada and outside the Field in the United States and Canada.

PLAN B: Licensing Arrangement

If KHK selects the licensing arrangement (Plan B), we will have the exclusive right to develop, manufacture and commercialize the Antibody Licensed Products in the Field in the United States, Canada and the European Union. We will be responsible for the manufacture of the Antibody Licensed Products for use by the parties in clinical trials as well as for commercialization in their respective fields and/or territories.

We will be required to pay KHK an initial license fee in the low single-digit millions of dollars upon the licensing arrangement becoming effective. We may pay KHK up to an additional $28 million upon the achievement of certain regulatory milestones related to the Antibody Licensed Products. The parties will split profits from our sales of Antibody Licensed Products in the United States, Canada and the European Union with us being entitled to approximately 74% of such profits and KHK being entitled to approximately 26% of such profits. KHK will pay us low double-digit royalties for sales of Antibody Licensed Products outside the United States, Canada and the European Union and outside the Field in the United States, Canada and the European Union. We will be responsible for costs of development of Antibody Licensed Products in the United States, Canada and the European Union. KHK will have the right to purchase the Antibody Licensed Products from us.

OCS Agreements

Under agreements with the OCS in Israel regarding research and development projects, our Israeli subsidiary committed to pay royalties to the OCS at rates between 3.5% and 5% of the income resulting from this research and development, at an amount not to exceed the amount of the grants received by our subsidiary as participation in the research and development program, plus interest at LIBOR. The obligation to pay these royalties is contingent on actual income and in the absence of such income no payment is required. As of December 31, 2017, the principal amount of the aggregate contingent liability amounted to approximately $13.97 million.

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

There has been no significant change in our exposure to market risk during the three months ended March 31, 2018. For a discussion of our exposure to market risk, refer to Part II, Item 7A, "Quantitative and Qualitative Disclosures About Market Risk," contained in our Annual Report on Form 10-K for the year ended December 31, 2017.

ITEM 4. Controls and Procedures

Evaluation of disclosure controls and procedures

As required by Rule 13a-15(b) of the Exchange Act, in connection with the filing of this Quarterly Report on Form 10-Q, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2018, the end of the period covered by this report.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the first quarter of 2018, which were identified in connection with management's evaluation required by paragraph (d) of Rules 13a-15 and 15d-15 under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. Legal Proceedings

We are not currently a party, as plaintiff or defendant, to any legal proceedings which, individually or in the aggregate, are expected by us to have a material effect on our business, financial condition or results of operation if determined adversely to us.

ITEM 1A. Risk Factors

The discussion of our business and operations should be read together with the risk factors contained in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 which describe various risks and uncertainties to which we are or may become subject. These risks and uncertainties have the potential to affect our business, financial condition, results of operations, cash flows, strategies or prospects in a material and adverse manner. There are no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017.

ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds

Recent Sales of Unregistered Securities

None

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None

ITEM 3. Defaults Upon Senior Securities

None

ITEM 4. Mine Safety Disclosures

Not applicable

ITEM 5. Other Information

On August 11, 2017, the Compensation Committee approved the grant of an option to Michael F. Cola, our President and Chief Executive Officer, to acquire 500,000 shares of our common stock, which was subsequently reported on a Form 4 filed by Mr. Cola on August 15, 2017. We determined that a number of shares subject to this option, when aggregated with an option award made earlier in calendar year 2017, exceeded the per person share limit under our Stock Incentive Plan, as amended, by 450,000 shares and were, therefore null and void. Mr. Cola has acknowledged the cancellation of the excess portion of such award to reduce the number of options shares granted to meet the plan limitation. On May 14, 2018, the Compensation Committee approved the grant of an option to Mr. Cola to acquire 450,000 shares of our common stock with an exercise price equal to $1.51 per share, the fair market value of our common stock on the date of grant.

On August 11, 2017, the Compensation Committee approved the grant of an option to Brian D. Piper, our Chief Financial Officer, to acquire 380,000 shares of our common stock, which was subsequently reported on a Form 4 filed by Mr. Piper on August 15, 2017. We determined that a number of shares subject to this option, when aggregated with an option award made earlier in calendar year 2017, exceeded the per person share limit under our Stock Incentive Plan, as amended, by 270,000 shares and were, therefore null and void. Mr. Piper has acknowledged the cancellation of the excess portion of such award to reduce the number of options shares granted to meet the plan limitation. On May 14, 2018, the Compensation Committee approved the grant of an option to Mr. Piper to acquire 270,000 shares of our common stock with an exercise price equal to $1.51 per share, the fair market value of our common stock on the date of grant.

On August 11, 2017, the Compensation Committee approved the grant of an option to Garry A. Neil, our Chief Scientific Officer, to acquire 400,000 shares of our common stock, which was subsequently reported on a Form 4 filed by Dr. Neil on August 15, 2017. We determined that a number of shares subject to this option, when aggregated with an option award made earlier in calendar year 2017, exceeded the per person share limit under our Stock Incentive Plan, as amended, by 300,000 shares and were, therefore null and void. Dr. Neil has acknowledged the cancellation of the excess portion of such award to reduce the number of options shares granted to meet the plan limitation. On May 14, 2018, the Compensation Committee approved the grant of an option to Dr. Neil to acquire 300,000 shares of our common stock with an exercise price equal to $1.51 per share, the fair market value of our common stock on the date of grant.

ITEM 6. Exhibits

Exhibit No.	Description
10.1	Form of Non-Qualified Stock Option Award Agreement under the Aevi Genomic Medicine, Inc. Stock Incentive Plan
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
101	Interactive Data File (filed herewith).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: May 15, 2018

AEVI GENOMIC MEDICINE, INC.

By: /s/ Michael F. Cola
Michael F. Cola
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 15, 2018

By: /s/ Brian D. Piper
Brian D. Piper
Chief Financial Officer and Corporate Secretary
(Principal Financial Officer)

Exhibit 10.1

*****FORM*****

AEVI GENOMIC MEDICINE, INC.

Stock Incentive Plan

Non-Qualified Stock Option Award Terms

The Participant specified below has been granted this Non-Qualified Option (the "**Option**") by **Aevi Genomic Medicine, Inc.**, a Delaware corporation (the "**Company**"), under the terms of the **Aevi Genomic Medicine, Inc. Stock Incentive Plan**, as amended from time to time (the "**Incentive Plan**"). The Option shall be subject to the Incentive Plan as well as the following terms and conditions (the "**Option Terms**"):

Terms of Award. The following words and phrases relating to the grant of the Option shall have the following meanings:

The "**Participant**" is XXXXX.

The "**Date of Grant**" is DATE.

The number of "**Covered Shares**" is XXX shares of Common Stock.

The "**Exercise Price**" is $X, the Closing Price of Stock on the Date of Grant.

Except for terms otherwise defined in the Option Terms, any capitalized term in the Option Terms shall have the meaning ascribed to that term under the Incentive Plan.

Non-Qualified Stock Option. The Option is intended to be a Non-qualified Stock Option and ***not*** intended to constitute an "incentive stock option" as that term is used in Code section 422.

Date of Exercise. Subject to the limitations of the Option Terms, each installment of Covered Shares ("**Installment**") shall become vested and exercisable on and after the "**Vesting Date**" for such Installment as described in the following schedule (but only if the Participant's Termination of Service has not occurred before the Vesting Date):

INSTALLMENT	VESTING DATE APPLICABLE TO INSTALLMENT
XXX	Year Anniversary of Date of Grant
XXX	2nd Year Anniversary of Date of Grant
XXX	3rd Year Anniversary of Date of Grant

Notwithstanding the foregoing provisions of this **0**, the Option shall become fully exercisable upon a Change in Control that occurs on or before the Participant's Termination of Service.

The Option may be exercised on or after the Participant's Termination of Service for any reason other than for Cause only as to that portion of the Covered Shares for which it was exercisable immediately prior to the Participant's Termination of Service, or became exercisable on the date of the Participant's Termination of Service.

Expiration. The Option shall not be exercisable after the Company's close of business on the last business day that occurs prior to the Expiration Date. The "**Expiration Date**" shall be the earliest to occur of:

10 years after date of grant; or

the twelve (12) month anniversary of the Participant's Termination of Service if such termination occurs due to death or Disability; or

the 90th day following Participant's Termination of Service if such termination occurs for any reason other than death, Disability or Cause; or

the effective date of a Termination of Service where such Termination of Service is for Cause.

For purposes of this Agreement, "**Cause**" shall have the meaning set forth in the employment agreement entered into by and between the Participant and the Company, if any. In the absence of any such agreement, "Cause" shall mean (1) any act by the Participant of (A) fraud or intentional misrepresentation, or (B) embezzlement, misappropriation or conversion of assets or opportunities of the Company or any Affiliate, or (2) any willful violation of any law, rule or regulation in connection with the performance of the Participant's duties (other than traffic violations or similar offenses), or (3) with respect to any employee of the Company or any Affiliate, commission of any act of moral turpitude or conviction of a felony, or (4) the willful or negligent failure of the Participant to perform his duties in any material respect.

Method of Option Exercise. Subject to the Option Terms and the Incentive Plan, the Option may be exercised in whole or in part by filing a written notice with the Secretary of the Company at its corporate headquarters prior to the Company's close of business on the last business day that occurs prior to the Expiration Date. Such notice shall specify the number of shares of Common Stock which the Participant elects to purchase, and shall be accompanied by payment of the Exercise Price for such shares of Common Stock indicated by the Participant's election. Payment may be by cash or, subject to limitations imposed by applicable law, by such means as the Committee from time to time may permit, provided that payment may be made by a net exercise such that, without the payment of funds, the Participant may exercise the Option and receive the net number of shares of Common Stock equal in value to (a) the number of shares as to which the Option is being exercised, multiplied by (b) a fraction, the numerator of which is the closing sales price of a share of Common Stock on the NASDAQ Global Market on the date of exercise less the Exercise Price, and the denominator of which is such closing sales price (the number of net shares to be received shall be rounded down to the nearest whole number of shares). The Option shall not be exercisable if and to the extent the Company determines that such exercise would violate applicable state or federal securities laws or the rules and regulations of any securities exchange on which the Common Stock is traded and shall not be exercisable during any blackout period established by the Company from time to time.

Withholding. The exercise of the Option, and the Company's obligation to issue shares of Common Stock upon exercise, is subject to withholding of all applicable taxes. As permitted by the Committee from time to time, such withholding obligations may be satisfied at the election of the Participant (a) through cash payment by the Participant, (b) through the surrender of shares of Common Stock that the Participant already owns or (c) through the surrender of shares of Common Stock to which the Participant is otherwise entitled under the Incentive Plan; *provided*, *however*, that except as otherwise specifically provided by the Committee, such shares under clause (c) may not be used to satisfy more than the Company's minimum statutory withholding obligation.

Transferability. The Option, or any portion thereof, is not transferable except as designated by the Participant by will or by the laws of descent and distribution or pursuant to a domestic relations order. Except as provided in the immediately preceding sentence, the Option shall not be assigned, transferred, pledged, hypothecated or otherwise disposed of by the Participant in any way whether by operation of law or otherwise, and shall not be subject to execution, attachment or similar process. Any attempt at assignment, transfer, pledge, hypothecation or other disposition of the Option contrary to the provisions hereof, or the levy of any attachment or similar process upon the Option, shall be null and void and without effect.

Heirs and Successors. The Option Terms shall be binding upon, and inure to the benefit of, the Company and its successors and assigns, and upon any person acquiring, whether by merger, consolidation, purchase of assets or otherwise, all or substantially all of the Company's assets and business. If any rights of the Participant or benefits distributable to the Participant under the Option Terms have not been exercised or distributed, respectively, at the time of the Participant's death, such rights shall be exercisable by the Beneficiary, and such benefits shall be distributed to the Beneficiary, in accordance with the provisions of the Option Terms and the Incentive Plan. The "**Beneficiary**" shall be the beneficiary or beneficiaries designated by the Participant in a writing filed with the Committee in such form and at such time as the Committee may require. The designation of beneficiary form may be amended or revoked from time to time by the Participant in accordance with such procedures as may be established by the Committee. If a Participant fails to designate a Beneficiary, or if the Beneficiary does not survive the Participant, any rights that would have been exercisable by the Participant and any benefits distributable to the Participant shall be exercised by or distributed to the legal representative of the estate of the Participant. If a Participant designates a beneficiary and the Beneficiary survives the Participant but dies before the Beneficiary's exercise of all rights under the Option Terms or before the complete distribution of benefits to the Beneficiary under the Option Terms, then any rights that would have been exercisable by the Beneficiary shall be exercised by the legal representative of the estate of the Beneficiary, and any benefits distributable to the Beneficiary shall be distributed to the legal representative of the estate of the Beneficiary.

Administration. The authority to manage and control the operation and administration of the Option Terms and the Incentive Plan shall be vested in the Committee, and the Committee shall have all powers with respect to the Option Terms as it has with respect to the Incentive Plan. Any interpretation of the Option Terms or the Incentive Plan by the Committee and any decision made by it with respect to the Option Terms or the Incentive Plan are final and binding on all persons.

Incentive Plan Governs. Notwithstanding anything in the Option Terms to the contrary, the Option Terms shall be subject to the terms of the Incentive Plan, a copy of which may be obtained by the Participant from the Secretary of the Company; and the Option Terms are subject to all interpretations, amendments, rules and regulations promulgated by the Committee from time to time pursuant to the Incentive Plan. Notwithstanding anything in the Option Terms to the contrary, in the event of any discrepancy between the corporate records of the Company and the Option Terms, the corporate records of the Company shall control.

Not An Employment Contract. The Option does not confer on the Participant any right with respect to continuance of employment or other service with the Company or any Affiliate, nor shall it interfere in any way with any right the Company or any Affiliate would otherwise have to terminate or modify the terms of such Participant's employment or other service at any time.

No Rights As Shareholder. The Participant shall not have any rights of a shareholder with respect to the Covered Shares subject to the Option until a stock certificate has been duly issued following exercise of the Option as provided herein.

Amendment. The Option Terms may be amended in accordance with the provisions of the Incentive Plan, and may otherwise be amended by written agreement of the Participant and the Company without the consent of any other person.

Validity. If any provision of the Option Terms is determined to be illegal or invalid for any reason, said illegality or invalidity shall not affect the remaining parts hereof, but the Option Terms shall be construed and enforced as if such illegal or invalid provision had never been included herein.

Section 409A Amendment. The Committee reserves the right (including the right to delegate such right) to unilaterally amend the Option Terms and the Incentive Plan without the consent of the Participant to maintain compliance with Code Section 409A. The Participant's acceptance of the Option constitutes acknowledgement and consent to such rights of the Committee.

Clawback. The Option and any amount or benefit received under the Incentive Plan shall be subject to potential cancellation, recoupment, rescission, payback or other similar action in accordance with the terms of any applicable Company clawback policy (the "**Policy**") or any applicable law. The Participant's acceptance of the Option constitutes acknowledgement and consent to the Company's application, implementation and enforcement of (a) the Policy and any similar policy established by the Company that may apply to the Participant and (b) any provision of applicable law relating to cancellation, rescission, payback or recoupment of compensation, as well as the Participant's express agreement that the Company may take such actions as are necessary to effectuate the Policy, any similar policy and applicable law, without further consideration or action.

IN WITNESS WHEREOF, the Company has caused the Option Terms to be executed in its name and on its behalf, and the Participant acknowledges understanding and acceptance of, and agrees to, the terms of the Option Terms, all as of the Date of Grant.

PARTICIPANT

Signature

Print Name

AEVI GENOMIC MEDICINE, INC.,

By:

Its:

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael F. Cola, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aevi Genomic Medicine, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

AEVI GENOMIC MEDICINE, INC.

Date: May 15, 2018

/s/ Michael F. Cola

Michael F. Cola
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brian D. Piper, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aevi Genomic Medicine, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

AEVI GENOMIC MEDICINE, INC.

Date: May 15, 2018

/s/ Brian D. Piper

Brian D. Piper
Chief Financial Officer and Corporate Secretary
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chapter 63, Title 18 U.S.C. § 1350(a) and (b)), each of the undersigned hereby certifies that, to his knowledge, the Quarterly Report on Form 10-Q for the period ended March 31, 2018 of Aevi Genomic Medicine, Inc. (the "Company") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 15, 2018

/s/ Michael F. Cola
Michael F. Cola
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 15, 2018

/s/ Brian D. Piper
Brian D. Piper
Chief Financial Officer and Corporate Secretary
(Principal Financial Officer)