**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 June 30, 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 August 1, 2018, the registrant had 59,340,731 shares of common stock, $0.0001 par value, outstanding.

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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)**

| | June 30, 2018 Unaudited | December 31, 2017 Audited |
|---|---|---|
| ASSETS | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | $ 19,151 | $ 33,729 |
| Prepaid expenses and other current assets | 855 | 893 |
| Total current assets | 20,006 | 34,622 |
| LONG-TERM ASSETS: | | |
| Lease deposits | 11 | 11 |
| Property and equipment, net | 53 | 85 |
| Other long-term assets | 163 | 43 |
| Total long-term assets | 227 | 139 |
| Total assets | $ 20,233 | $ 34,761 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| CURRENT LIABILITIES: | | |
| Trade payables | $ 1,463 | $ 943 |
| Other accounts payable and accrued expenses | 3,480 | 3,197 |
| Total current liabilities | 4,943 | 4,140 |
| Total liabilities | 4,943 | 4,140 |
| STOCKHOLDERS' EQUITY: | | |
| Common stock - $0.0001 par value; 200,000,000 shares authorized; 59,340,731 shares issued and outstanding at June 30, 2018; 59,332,265 shares issued and outstanding at December 31, 2017 | $ 6 | $ 6 |
| Additional paid-in capital | 247,162 | 245,593 |
| Accumulated deficit | (231,878) | (214,978) |
| Total stockholders' equity | 15,290 | 30,621 |
| Total liabilities and stockholders' equity | $ 20,233 | $ 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)**

| | Six months ended June 30, | | Three months ended June 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| | Unaudited | | Unaudited | |
| Research and development expenses | $ 12,308 | $ 13,614 | $ 5,747 | $ 5,667 |
| General and administrative expenses | 4,678 | 5,357 | 2,504 | 2,369 |
| Operating loss | (16,986) | (18,971) | (8,251) | (8,036) |
| Financial income | 86 | 21 | 60 | 3 |
| Net loss | $ (16,900) | $ (18,950) | $ (8,191) | $ (8,033) |
| Basic and diluted loss per share | $ (0.28) | $ (0.51) | $ (0.14) | $ (0.22) |
| Weighted average number of common stock used in computing basic and diluted loss per share | 59,336,547 | 37,109,157 | 59,338,255 | 37,110,043 |

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)**

| | Six months ended June 30, | |
|---|---|---|
| | **2018** | **2017** |
| | **Unaudited** | |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | $ (16,900) | $ (18,950) |
| Adjustments to reconcile loss to net cash used in operating activities: | | |
| Depreciation | 32 | 81 |
| Stock-based compensation | 1,535 | 1,775 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | 38 | (740) |
| Trade payables | 520 | 1,744 |
| Other accounts payable and accrued expenses | 283 | (2,410) |
| Other long term assets | 43 | - |
| Net cash used in operating activities | $ (14,449) | $ (18,500) |
| 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 |
| Deferred offering costs | (163) | - |
| Net cash (used in) provided by financing activities | $ (129) | $ 19 |
| Decrease in cash and cash equivalents | (14,578) | (18,481) |
| 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 | $ 19,151 | $ 21,357 |

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 six-month period ended June 30, 2018 of $16,900 and $14,449, respectively. The accumulated deficit as of June 30, 2018 was $231,878. As of June 30, 2018, the Company had cash and cash equivalents of $19,151. Based upon current management projections, the Company expects the current cash balance to fund operations into early in 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 June 30, 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.

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 third parties. As of June 30, 2018, the Company had cash and cash equivalents of $19,151 and liabilities of $4,943. On May 15, 2018, the Company entered into an Equity Distribution Agreement pursuant to which it may from time-to-time issue and sell shares of Company common stock having an aggregate offering price of up to $20,000 in an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act (the "ATM Facility"). The Company did not sell any shares of common stock under the ATM Facility during the three months ended June 30, 2018.

The Company has incurred recurring operating losses since inception. For the three and six months ended June 30, 2018, the Company incurred a net loss of $8,191 and $16,900, respectively, and as of June 30, 2018 the Company has an accumulated deficit of $231,878. 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 remaining payments totaling $2,375 will be due in the second half of 2018 and $2,375 will be due in the first half of 2019. In June 2018, the Company again extended the Research Agreement, with an amendment covering the period from July 1, 2019 through June 30, 2020, for which incremental payments totaling $2,375 will be due in the second half of 2019 and $2,375 will be due in the first half of 2020. Expenses related to CHOP, within a sponsored research agreement or otherwise, were $1,839 and $4,427 for the three and six month periods ended June 30, 2018, respectively, and $1,578 and $3,717 for the three and six month periods ended June 30, 2017, respectively. As of June 30, 2018, the Company has total payables related to CHOP, inclusive of those related to the sponsored research agreement, of $959, allocated between accrued expenses and trade payables.

(In thousands, except share and per share data)

**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:

| | Six months ended June 30, 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 | 2,935,930 | $ 1.54 | | |
| Exercised | (17,334) | $ 1.24 | | |
| Forfeited | (3,174,097) | $ 3.17 | | |
| Outstanding at June 30, 2018 | 10,854,861 | $ 3.93 | 7.17 | $ - |
| Vested and expected to vest at June 30, 2018 | 10,854,861 | $ 3.93 | 7.17 | $ - |
| Exercisable at June 30, 2018 | 6,450,074 | $ 5.01 | 5.70 | $ - |

As of June 30, 2018, there was $4,686 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 1.88 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:

| | Six months ended June 30, 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 | (164,000) | $ 3.37 | | |
| Outstanding at June 30, 2018 | 36,000 | $ 2.44 | 9.23 | $ - |
| Vested and expected to vest at June 30, 2018 | 36,000 | $ 2.44 | 9.23 | $ - |
| Exercisable at June 30, 2018 | 36,000 | $ 2.44 | 9.23 | $ - |

(In thousands, except share and per share data)

As of June 30, 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:

| | Six months ended June 30, | | Three months ended June 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Research and development expenses | $ 646 | $ 765 | $ 314 | $ 320 |
| General and administrative expenses | 889 | 1,010 | 472 | 454 |
| | $ 1,535 | $ 1,775 | $ 786 | $ 774 |

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 June 30, 2018 is presented in the following table:

| | | As of June 30, 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 | 3,660,480 | 295,418 | 9.6 |
| | 3.14-5.07 | 4,574,233 | 3,693,632 | 6.5 |
| | 5.22-8.80 | 2,478,938 | 2,319,814 | 5.0 |
| | | 10,713,651 | 6,308,864 | |
| | | | | |
| Granted to consultants | | | | |
| | 1.52 | 26,000 | 26,000 | 9.6 |
| | 4.82 | 10,000 | 10,000 | 8.3 |
| | | 36,000 | 36,000 | |
| | | | | |
| Total shares to be issued upon exercise of options | | 10,749,651 | 6,344,864 | |
| | | | | |
| Warrants: | | | | |
| | | | | |
| Issued to employees and directors | 2.84 | 141,210 | 141,210 | 4.3 |
| | | | | |
| Issued to investors | 2.84 | 3,812,694 | 3,812,694 | 4.3 |
| | | | | |
| Total shares to be issued upon exercise of warrants | | 3,953,904 | 3,953,904 | |
| | | | | |
| Total shares to be issued upon exercise of options and warrants | | 14,703,555 | 10,298,768 | |

(In thousands, except share and per share data)

**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 six and three months ended June 30, 2018 and 2017:

| | Six months ended June 30, | | Three months ended June 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Weighted-average anti-dilutive shares related to: | | | | |
| Outstanding stock options | 10,014,390 | 11,038,485 | 9,753,033 | 11,306,828 |
| Outstanding warrants | 4,825,838 | 4,799,797 | 4,053,904 | 4,691,405 |
| | 14,840,228 | 15,838,282 | 13,806,937 | 15,998,233 |

**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.

**AEVI-001 (mGluR+ Genetic Subset Attention Deficit Hyperactivity Disorder ("ADHD")) and AEVI-004**

Our lead program, AEVI-001, is an oral, non-stimulant glutamatergic neuromodulator which completed a Phase 2/3 trial (SAGA) in adolescent Attention Deficit Hyperactivity Disorder, 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 ADHD-RS improvement of 30% or more [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 32% 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 (the "ASCEND" trial) in the mGluR mutation positive genetic subset ADHD ("mGluR+ Genetic Subset ADHD") to confirm genetic responders to AEVI-001. We recently announced that the sample size for Part A of the trial, which is enrolling a genetic subset of pediatric and adolescent mGLuR+ ADHD patients, will be increased from 42 to 64 patients. The decision to increase the sample size was made according to the protocol-defined sample size re-estimation design, which allows an adjustment in the sample size after an interim analysis of the placebo arm to ensure the trial is appropriately powered.

We are also exploring a development opportunity for AEVI-001 for the treatment of mGluR+ ADHD patients with ASD to better define the patient phenotype and intend to initiate work on a proof-of-concept study in the second half of 2018. In 2014, approximately1 in 59 children were diagnosed with ASD in the United States, increasing from 1 in 150 in 2000. There are currently limited pharmacotherapy options available to treat ASD and as a result 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.

**AEVI-004 (improved version (fasoracetam co-crystal) of AEVI-001)**

In June 2018 we announced that we received positive feedback from the United States Food and Drug Administration (the "FDA") on an improved version of our lead development molecule, AEVI-001, identified as AEVI-004.

Following 2016 FDA regulatory guidance on co-crystalization of active drugs, we created a co-crystal of fasoracetam (AEVI-001) with enhanced physical and chemical properties. The new molecule, AEVI-004, has comparatively greater stability and a higher melting point than AEVI-001. The molecule was engineered to maintain solubility, dissolution and pharmacokinetics substantially similar to AEVI-001.

We have received feedback from the FDA provisionally indicating that AEVI-004 is a co-crystal of AEVI-001 and a novel drug substance. The FDA also provisionally indicated that existing toxicology and pathology studies can support clinical development with minimal preclinical bridging studies for AEVI-004.

Assuming positive results from the ongoing Phase 2 ASCEND clinical trial, and following minimal bridging preclinical and clinical pharmacological studies requested by the FDA, we anticipate progressing the molecule directly into Phase 3 clinical trials.

AEVI-004 is expected to have composition of matter patents extending to 2039 and should be listed as a new chemical entity in the FDA Orange Book.

***AEVI-002 (Anti-LIGHT Monoclonal Antibody)***

Our second program is 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 (POC) study was initiated at CHOP in 2017, 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 POC study will include endoscopic evaluation, Crohn's Disease Activity Index ratings and safety. Active recruitment for the POC study is underway at four clinical trial sites in the United States, although the identification and recruitment of patients into the POC study has been extremely challenging, and to date no patients have been enrolled. To address the continued enrollment challenges for this program, we are evaluating the addition of clinical trial sites outside the United States. Assuming a small number of patients can be enrolled by the end of the third quarter 2018, initial data from a small number of patients would be expected by year-end 2018.

*AEVI-005*

AEVI-005 is the second monoclonal antibody in development as part of our ongoing collaboration with Kyowa Hakko Kirin. This program will focus on an undisclosed, first-in-class monoclonal antibody targeting a specific cell surface marker implicated in an auto-immune ultra-orphan disease that primarily affects children. We initiated a preclinical research program for AEVI-005 during the second quarter of 2018.

**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 $16.90 million for the six-month period ended June 30, 2018. As of June 30, 2018, we had stockholders' equity of approximately $15.29 million. As of June 30, 2018, we had cash and cash equivalents of $19.15 million. Based upon current management projections, we expect the current cash balance to fund operations into early in 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 on 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 the issuance of equity and/or debt securities, strategic collaborations and license arrangements. 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 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. 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, such as CHOP, 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, as well as cost of development and manufacturing of the drug supply for such studies. Research and development expenses will likely increase as we raise funding to 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 studies and 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.

***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 Six Months Ended June 30, 2018 and 2017**

***Research and Development Expenses***

Research and development expenses for the six months ended June 30, 2018 were $12.31 million, decreasing from $13.61 million for the same period in 2017 mainly related to decreasing clinical trials/development and research activities.

***General and Administrative Expenses***

General and administrative expenses for the six months ended June 30, 2018 were $4.68 million, decreasing from $5.36 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 six months ended June 30, 2018 and 2017 were de minimis.

**Results of Operations for the Three Months Ended June 30, 2018 and 2017**

***Research and Development Expenses***

Research and development expenses for the three months ended June 30, 2018 were $5.75 million, approximately equivalent to $5.67 million for the same period in 2017.

***General and Administrative Expenses***

General and administrative expenses for the three months ended June 30, 2018 were $2.50 million, approximately equivalent to $2.37 million for the same period in 2017.

***Financial Income and Expenses***

Financial income for the three months ended June 30, 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 third parties. On May 15, 2018, we entered 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"). We did not sell any shares of common stock under the ATM Facility during the three months ended June 30, 2018.

***Cash Flows***

We had cash and cash equivalents of $19.15 million at June 30, 2018, compared to $33.73 million as of December 31, 2017. The decrease in cash during the three months ended June 30, 2018 was primarily related to the advancement of our AEVI-001 program.

Net cash used in operating activities of $14.45 million for the six months ended June 30, 2018 and $18.50 million for the six months ended June 30, 2017 primarily reflected our cash expenses for our operations.

Net cash provided by and used in investing activities for the six months ended June 30, 2018 and 2017 were de minimis.

Net cash used in financing activities of $0.13 million for the six months ended June 30, 2018 and net cash provided by financing activities in the six months ended June 30, 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. 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.

Based upon current management projections, we expect the current cash balance to fund operations into early in the first quarter of 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. We do not anticipate that we will generate revenue from the sale of products for several years or more, if at all, given the uncertainty of drug development. 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. 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 six months ended June 30, 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 June 2017, we entered into an amendment to the Research Agreement, which extended the Research Agreement through June 30, 2019, for which remaining payments totaling $2.38 million will be due in the second half of 2018 and $2.38 million will be due in the first half of 2019. In June 2018, we again extended the Research Agreement, with an amendment covering the period from July 1, 2019 through June 30, 2020, for which incremental payments totaling $2.38 million will be due in the second half of 2019 and $2.38 million will be due in the first half of 2020.

***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 six months ended June 30, 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 June 30, 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 second 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**

**Business-Related Risks**

**Our recurring losses from operations raise substantial doubt regarding our ability to continue as a going concern.**

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern. There is no assurance that sufficient financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

**We are a clinical stage biopharmaceutical company and have a history of significant and continued operating losses and a substantial accumulated earnings deficit and we may continue to incur significant losses and may never achieve or maintain profitability.**

We are a clinical stage biopharmaceutical company and since our inception have been focused on research and development and have not generated any substantial revenues. We have incurred net losses of approximately $34.71 million, $41.90 million and $37.99 million for the years ended December 31, 2017, 2016 and 2015, respectively. As of June 30, 2018, we had stockholders' equity of approximately $15.29 million. We expect to incur significant expenses and increasing operating losses, as well as negative cash flow from operations, for the foreseeable future, as we continue to expand our research and development and commence commercialization of our potential product candidates. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. It could be several years, if ever, before we have a commercialized product. Our ability to generate revenues from sales of our potential products will depend on:

- successful completion of necessary clinical trials;
- regulatory approval;
- commercialization (through partnership or licensing deals or through internal development) and market acceptance of new technologies and product candidates under development;

- medical community awareness; and
- changes in regulation or regulatory policy.

**We will need substantial additional capital for the continued development of our product candidates and for our long-term operations.**

As of June 30, 2018, our cash and cash equivalents were approximately $19.15 million. Based upon current management projections, we expect the current cash balance to fund operations into early in the first quarter of 2019. However, changes in our business, whether or not initiated by us, may affect the rate at which we deplete our cash and cash equivalents. Our present and future capital requirements depend on many factors, including:

- the rate and level of patient recruitment into our clinical trials, particularly those in Phase 2 and Phase 3 stages of development, including those trials for which we are currently recruiting; for example, the identification and recruitment of patients into the ongoing AEVI-002 proof-of-concept clinical trial has been challenging. No patients have yet been recruited into the clinical trial. The ability to produce initial data by year-end 2018 is directly based on timely recruiting; thus, continued difficulties in recruitment could cause a delay in the delivery of data for the program, and potentially result in increased costs to complete the study;
- the level of research and development investment required to develop our product candidates;
- changes in product development plans needed to address any difficulties that may arise in manufacturing, pre-clinical activities, clinical trials or commercialization;
- our ability and willingness to enter into new agreements with strategic partners, and the terms of these agreements;
- our success rate in pre-clinical and clinical efforts;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- costs of recruiting and retaining qualified personnel;
- the timing and amount of milestone payments we are required to make under our license agreements;
- time and costs involved in obtaining regulatory approvals; and
- costs of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights.

We will require significant amounts of additional capital in the future, and such capital may not be available when we need it on terms that we find favorable, if at all. Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete. We may never progress to the point where we have commercially successful product sales which generate sufficient commercial revenue or such revenue may not be achieved for many years. Accordingly, we may seek to raise these funds through public or private equity offerings, debt financings, credit facilities, or partnering or other corporate collaborations and licensing arrangements. If adequate funds are not available or are not available on acceptable terms, our ability to fund our operations, take advantage of opportunities, develop products and technologies, and otherwise respond to competitive pressures could be significantly delayed or limited, and we may need to downsize or halt our operations.

**Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights.**

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings and debt financings. We do not have any committed external source of funds. We may seek additional capital through a combination of private and public equity offerings, debt financings, collaborations and strategic and licensing arrangements. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, the ownership interest of our stockholders in our company will be diluted. In addition, the terms of any such securities may include liquidation or other preferences that materially adversely affect the rights of our stockholders. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we raise additional funds through collaboration, strategic partnerships and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, our intellectual property, future revenue streams or grant licenses on terms that are not favorable to us.

**We are still in the process of clinical trials and do not have a commercialized product and may never be able to commercialize our product candidates.**

Only a small number of research and development programs ultimately result in commercially successful drugs and drug delivery systems. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons, including:

- failure to obtain regulatory approvals for AEVI-001, AEVI-002 or any of our product candidates or companion products;
- lack of familiarity of health care providers and patients;
- low market acceptance as a result of lower demonstrated clinical safety or efficacy compared to other products or other potential disadvantages relative to alternative treatment methods;
- inability to obtain favorable coverage determinations from health plans and third-party payers;
- insufficient or unfavorable levels of reimbursement from government or third-party payers;
- infringement on proprietary rights of others for which we (or our licensees, if any) have not received licenses;
- incompatibility with other therapeutic products;
- potential advantages of alternative treatment methods;
- ineffective marketing and distribution support;
- lack of cost-effectiveness; or
- timing of market introduction of competitive products.

If any of these potential problems occur, we may never successfully commercialize our product candidates, including AEVI-001 and AEVI-002. If we are unable to develop commercially viable products, our business, results of operations and financial condition will be materially and adversely affected.

**We have limited history as an organization in conducting clinical trials.**

We have limited history as an organization in conducting advanced clinical trials and may not possess the necessary resources and expertise to complete such trials, and we may need to seek additional partnerships or collaborations with third parties to advance these trials. Our most advanced clinical program is an ongoing Phase 2 trial in mGluR+ Genetic Subset ADHD to confirm genetic responders to AEVI-001. For potential marketing application approval, additional clinical testing will be required, which involves significantly greater resources, commitments and expertise and so it is likely that we would need to enter into a collaborative relationship with a pharmaceutical company that could assume responsibility for late-stage development and commercialization.

**Our product candidates are still being developed and have not been tested on a large patient population, and, therefore, we do not know all of the possible adverse events and may not be able to commercialize our product candidates as planned.**

Our product candidates have not been tested on a large number of patients, and are still in an early stage of development. While we have attained acceptable adverse event profile (or safety results) in our early stages of development and early clinical trials for AEVI-001, our product candidates are not yet fully developed or proven, and disappointing results and problems could delay or prevent the completion of our development programs and commercialization of our product candidates.

Our previous safety tests and results obtained in previous clinical trials of our product candidates may not be representative of either a larger multi-centric test or the commercial version of the technology in the general population. Specifically, the Phase 1b clinical trial for AEVI-001 completed prior to our acquisition of neuroFix was conducted on a single-blinded basis and may have been subject to bias and such results may not be replicated in a double-blinded clinical trial. In addition, the full impact of our product candidates, and their many possible variations, on the body is, as yet, unknown.

Treatment-related adverse events or complications in clinical trials, or post-approval, could result in limitations on the use of our product candidates and may also result in financial claims and losses against us, damage our reputation, and increase our expenses and reduce our assets. In addition, our product candidates may not gain commercial acceptance or ever be commercialized.

**We are currently dependent upon the successful development of our lead product candidates, AEVI-001 and AEVI-002. If we or our strategic partners, licensees and sublicensees fail to successfully complete their development and commercialization, we will not generate operating revenues.**

A substantial portion of our efforts and expenses are currently focused on the development of AEVI-001 and AEVI-002. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of AEVI-001 and AEVI-002. There is no guarantee that we will succeed in developing AEVI-001 or AEVI-002. If the development of both AEVI-001 and AEVI-002 fails, we may be unable to generate any revenues. There is no certainty as to our success, whether within a given time frame or at all. Any delays in our schedule for clinical trials, regulatory approvals or other stages in the development of our technology are likely to cause us additional expense and may even prevent the successful commercialization of any or all of our product candidates. Delays in the timing for development of our technology may also have a material adverse effect on our business, financial condition and results of operations due to the possible absence of financing sources for our operations during such additional periods of time. Although we may pursue other technologies (either developed in-house or acquired), there is no assurance that any other technology will be successfully identified or exploited.

**Clinical trials involve lengthy and expensive processes with uncertain outcomes, and results of earlier studies and trials may not be predictive of future trial results.**

The risk of failure of our product candidates is high. We cannot predict whether we will encounter problems with any of our completed, ongoing, planned or future clinical trials, which would cause us or regulatory authorities to delay or suspend clinical trials, or delay the analysis of data from completed or ongoing clinical trials. The FDA Reauthorization Act, signed into law in August 2017, authorizes FDA to impose additional clinical trial requirements on manufacturers seeking orphan drug designation and/or pediatric indications. The impact of these future regulations is uncertain and could result in the need for additional clinical trials. We estimate that clinical trials involving AEVI-001 and AEVI-002 will continue for several years; however, such trials may also take significantly longer to complete and may cost more money than we expect. Failure can occur at any stage of testing, and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of the current, or a future, more advanced, version of our product candidates, including but not limited to:

- delays in obtaining regulatory approvals to commence a clinical trial;
- failure or inability to recruit qualified investigators;
- difficulty finding qualified patients for clinical studies, including slower than anticipated patient recruitment and enrollment;

- negative or inconclusive results from clinical trials;
- inability, delay, or failure in identifying and maintaining a sufficient number of trial sites, many of which may already be engaged in other clinical programs;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical studies and increased expenses associated with the services of our clinical research organizations, or CROs, and other third parties;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- there may be changes in governmental regulations or administrative actions;
- unforeseen safety issues;
- an inability to monitor patients adequately during or after treatment; and
- problems with investigator or patient compliance with the trial protocols.

A number of companies in the biopharmaceutical and pharmaceutical industries including those with greater resources and experience than us have suffered significant setbacks in advanced clinical trials, even after seeing promising results in earlier clinical trials. We do not know whether any clinical trials we or any future clinical partners may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market AEVI-001, AEVI-002 or any other product. If subsequent clinical trials involving AEVI-001 or AEVI-002 do not produce favorable results, we may be required to perform additional clinical trials or our ability to obtain regulatory approval may be adversely impacted, either of which would have an adverse material effect on our business, financial condition and the results of our operations.

**Potential difficulty with, and delays in, recruiting patients for human clinical trials may adversely affect the timing of our clinical trials and our working capital requirements.**

Our research and development is highly dependent on timely recruitment of the requisite number and type of patients for our clinical trials. We have previously found it very difficult to recruit such patients, and the increased volume and ethnic backgrounds required for future testing may render such testing even more difficult. Such larger studies will likely be based on the use of multicenter, multinational design, which can prove difficult to manage and could result in delays in patient recruitment. In addition, as we pursue development of our product candidates in orphan and rare disease applications, including for pediatric populations, we may find it difficult to find sufficient treatment-naïve patients needed for initial trials, especially within commercially-reasonable geographical regions. Delays in the recruitment of such patients could delay our trials and negatively impact our working capital requirements and ability to raise capital.

**We may not successfully establish and maintain relationships with third-party service providers and collaborators, which could adversely affect our ability to develop, manufacture and commercialize our product candidates.**

Our ability to develop and commercialize our product candidates is dependent on our ability to reach strategic licensing and other development agreements with appropriate partners, including biopharmaceutical and pharmaceutical companies and CROs. If we are unable to successfully negotiate such agreements, we may not be able to continue to develop our product candidates, including AEVI-001 and AEVI-002, without raising significant additional capital for development and commercialization.

Our core business strategy is to develop our product candidates for use in specific indications and disease markets that we would internally develop and launch. However, we do plan to explore collaborative relationships or strategic partnerships and/or license our product candidates. We may not be able to identify such collaborators and partners on a timely basis, and we may not be able to enter into relationships with any future collaborator(s) or partner(s) on terms that are commercially beneficial to us or at all. In addition, such relationships and partnerships may not come to fruition or may not be successful. Our agreements with these third parties may also contain provisions that restrict our ability to develop and test our product candidates or that give third parties rights to control aspects of our product development and clinical programs.

The third-party contractors may not assign as great of a priority to our clinical development programs or pursue them as diligently as we would if we were undertaking such programs directly and, accordingly, may not complete activities on schedule, or may not conduct the studies or our clinical trials in accordance with regulatory requirements or with our trial design. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if their performance is substandard, we may be required to replace them.

In addition, conflicts may arise with our collaborators (e.g. those concerning the interpretation of clinical data), the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. If any conflicts arise with our existing or future collaborators, they may act in their self-interest, which may be adverse to our best interests. The third-party contractors may also have relationships with other commercial entities, some of whom may compete with us. If the third-party contractors work with our competitors, our competitive position may be harmed.

In addition, although we attempt to audit and control the quality of third-party data, we cannot guarantee the authenticity or accuracy of such data, nor can we be certain that such data has not been fraudulently generated. The failure of third parties to carry out their obligations towards us would materially adversely affect our ability to develop and market product candidates.

**We have no marketing experience, sales force or distribution capabilities. If our product candidates are approved, and we are unable to recruit key personnel to perform these functions, we may not be able to successfully commercialize the products.**

Although we do not currently have any marketable products, our ability to produce revenues ultimately depends on our ability to commercialize our product candidates if and when they are approved by the FDA and/or other regulatory health agencies. We currently do not have a marketing and sales staff or distribution capabilities. Developing a marketing and sales force is also time-consuming and expensive and these costs may be incurred in advance of any approval of our product candidates. Failure to develop these capabilities could delay the launch of new products or expansion of existing product sales. In addition, we will compete with many companies that currently have extensive and well-funded marketing, sales and distribution operations. If we fail to establish successful marketing, sales and distribution capabilities or fail to enter into successful marketing sales or distribution arrangements with third parties, our ability to generate revenues will suffer.

Furthermore, even if we enter into marketing, sales and distributing arrangements with third parties, these third parties may not be successful or effective in marketing, selling or distributing our product candidates. If we fail to create successful and effective marketing, sales and distribution channels, our ability to generate revenue and achieve our anticipated growth could be adversely affected. If these distributors experience financial or other difficulties, sales of our products could be reduced, and our business, financial condition and results of operations could be harmed.

**We are subject to intense government regulation and we may not be able to successfully complete the necessary clinical trials.**

Approval for clinical trials depends, among other things, on data obtained from our pre-clinical and clinical activities, including completion of pre-clinical animal and *in vitro* studies in a timely manner. These pre-clinical and clinical activities must meet stringent quality assurance and compliance requirements. Data obtained from such activities are susceptible to varying interpretations, which could delay, limit or prevent regulatory approvals.

We currently have limited experience in and resources for conducting the large-scale clinical trials which may hamper our ability to obtain or comply with regulatory approval. The failure to comply with applicable regulatory requirements may result in criminal prosecution, civil penalties, product recalls, withdrawal of product approval, mandatory restrictions and other actions, which could impair our ability to conduct business.

**Use of third parties to manufacture our product candidates or diagnostics may increase the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost or that development of the diagnostics will be delayed. Clinical development and commercialization of our product candidates could be delayed, prevented or impaired.**

We do not own or operate manufacturing facilities for production of our product candidates or diagnostics. We lack the resources and the capabilities to manufacture any of our product candidates or diagnostics on a clinical or commercial scale. We currently outsource the manufacturing and packaging of our pre-clinical and clinical product candidates to third parties and if we pursue a diagnostic product, we anticipate that we would outsource manufacturing to a third party. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields and quality control, including stability of the product candidate. The occurrence of any of these problems could significantly delay our clinical trials or the commercial availability of our products.

We do not currently have any agreements with third party manufacturers for the long-term commercial supply of any of our product candidates or agreements with any third party for development of diagnostics. We may be unable to enter into agreements for development and commercial supply with third party manufacturers or with a third party for development of diagnostics, or may be unable to do so on acceptable terms. Even if we enter into these agreements, the manufacturers of each product candidate and developer of diagnostics will likely be single source suppliers to us for a significant period of time.

Reliance on third party manufacturers entails risks, to which we would not be subject if we manufactured product candidates or products ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;
- limitations on supply availability resulting from capacity and scheduling constraints of the third parties;
- impact on our reputation in the marketplace if manufacturers of our products, once commercialized, fail to meet the demands of our customers;
- the quality or stability of the product candidates falling below acceptable standards;
- the inability to produce sufficient quantities of our product candidates;
- the timely development of the required diagnostics;
- exceeding budgeted costs due to difficulties in accurately predicting such costs or other factors impacting the cost of manufacturing our product candidates or developing diagnostics;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control; and
- the possible termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

The failure of any of our contract manufacturers to maintain high manufacturing standards could result in injury or death of clinical trial participants or patients using products. Such failure could also result in product liability claims, product recalls, product seizures or withdrawals, delays or failures in testing or delivery, cost overruns or other problems that could seriously harm our business or profitability.

Our contract manufacturers are required to adhere to FDA regulations setting forth cGMP. These regulations cover all aspects of the manufacturing, testing, quality control and recordkeeping relating to our product candidates and any products that we may commercialize. Our manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure or the failure of our third party manufacturers, to comply with applicable regulations could significantly and adversely affect regulatory approval and supplies of our product candidates.

Our product candidates and any products that we may develop or acquire may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. If the third parties that we engage to manufacture products for our pre-clinical tests and clinical trials should cease to continue to do so for any reason, we likely would experience delays in advancing these trials while we identify and qualify replacement suppliers and we may be unable to obtain replacement supplies on terms that are favorable to us. Later relocation to another manufacturer will also require notification, review and other regulatory approvals from the FDA and other regulators and will subject our production to further cost and instability in the availability of our product candidates. In addition, if we are not able to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop product candidates and commercialize any products that obtain regulatory approval on a timely and competitive basis.

**Materials necessary to manufacture our product candidates may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our product candidates.**

We rely on the manufacturers of our product candidates to purchase from third party suppliers the materials necessary to produce the compounds for our preclinical and clinical studies and will rely on these other manufacturers for commercial distribution if we obtain marketing approval for any of our product candidates. Suppliers may not sell these materials to our manufacturers at the time we need them or on commercially reasonable terms and all such prices are susceptible to fluctuations in price and availability due to transportation costs, government regulations, price controls and changes in economic climate or other foreseen circumstances. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these materials. If our manufacturers are unable to obtain these materials for our preclinical and clinical studies, product testing and potential regulatory approval of our product candidates would be delayed, significantly impacting our ability to develop our product candidates. If our manufacturers or we are unable to purchase these materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would materially affect our ability to generate revenues from the sale of our product candidates.

**We may not be successful in our efforts to in-license or acquire additional product candidates.**

A significant element of our strategy is to build and expand our pipeline of product candidates through in-licensing or acquiring additional product candidates. Currently, we do not have the internal expertise, nor do we intend to develop the internal expertise, necessary to discover new chemical entities for therapeutic purposes. As a result, if we are not able to identify and acquire additional product candidates, we will not be able to expand our pipeline. Even if we are successful in continuing to build our pipeline through in-licensing or acquisitions, the potential product candidates that we in-license or acquire may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval and achieve market acceptance.

**Our business activities involve the use of hazardous materials, which require compliance with environmental and occupational safety laws regulating the use of such materials. If we violate these laws, we could be subject to significant fines, liabilities or other adverse consequences.**

Our research and development programs involve the controlled use of hazardous materials, including microbial agents and other hazardous compounds in addition to certain biological hazardous waste. Ultimately, the activities of our third party product manufacturers when a product candidate reaches commercialization will also require the use of hazardous materials. Accordingly, we are subject to federal, state and local laws governing the use, handling and disposal of these materials. Although we believe that our safety procedures for handling and disposing of these materials comply in all material respects with the standards prescribed by local, state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In addition, our collaborators may not comply with these laws. In the event of an accident or failure to comply with environmental laws, we could be held liable for damages that result, and any such liability could exceed our assets and resources or we could be subject to limitations or stoppages related to our use of these materials which may lead to an interruption of our business operations or those of our third-party contractors. While we believe that our existing insurance coverage is generally adequate for our normal handling of these hazardous materials, it may not be sufficient to cover pollution conditions or other extraordinary or unanticipated events. Furthermore, an accident could damage or force us to shut down our operations. Changes in environmental laws may impose costly compliance requirements on us or otherwise subject us to future liabilities and additional laws relating to the management, handling, generation, manufacture, transportation, storage, use and disposal of materials used in or generated by the manufacture of our products or related to our clinical trials. In addition, we cannot predict the effect that these potential requirements may have on us, our suppliers and contractors or our customers.

**The FDA and other regulatory health agencies will regulate our product candidates and we may never receive regulatory approval to market and sell our product candidates.**

Our product candidates will require regulatory approvals prior to sale. In particular, our product candidates are subject to stringent approval processes, prior to commercial marketing, by the FDA and other regulatory health agencies in all countries where we operate and desire to introduce our product candidates, whether sold via a strategic partner or directly by us. These requirements range from efficacy and safety assessments in multiple clinical trials to long-term follow-up assessments on treated patients in clinical trials for product approval for sale. The process of obtaining FDA and corresponding foreign approvals is costly and time-consuming, and we cannot assure that such approvals will be granted. Also, the regulations we are subject to change frequently and such changes could cause delays in the development of our product candidates.

It typically takes a company several years or longer to satisfy the substantial requirements imposed by the FDA and other regulatory health agencies in other countries for the introduction of therapeutic pharmaceutical and biological products. Pharmaceutical or biological products must be registered in accordance with applicable law before they can be manufactured, marketed and distributed. This registration must include medical data proving the product's safety, efficacy and clinical testing. Also included in product registration should be references to medical publications and information about the production methods and quality control.

To obtain regulatory approvals in the United States or other jurisdictions, we or a collaborator must ultimately demonstrate to the satisfaction of the FDA and other health regulatory agencies that our product candidates are sufficiently safe and effective for their proposed administration to humans. Many factors, both known and unknown, can adversely impact the development of our product candidates and our ability to obtain regulatory approval for our product candidates, including:

- the FDA or other health regulatory authorities or instructional review boards decision(s) not to approve a clinical trial protocol or place a clinical trial on hold;
- suitable patients not enrolling in a clinical trial in sufficient numbers or at the expected rate, for reasons such as the size of the prospective patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the perceptions of investigators and patients regarding safety, and the availability of other treatment options;
- clinical trial data being adversely affected by trial conduct or patient withdrawal prior to completion of the trial;
- competition with ongoing clinical trials and scheduling conflicts with participating clinicians;
- patients that experience adverse events, including treatment-related adverse events of our product candidates, for a variety of reasons that may or may not be related to our product candidates, including the advanced stage of their disease and other medical problems;
- patients in the placebo or untreated control group exhibiting greater than expected improvements or fewer than expected adverse events;
- third-party clinical investigators not performing the clinical trials on the anticipated schedule or consistently with the clinical trial protocol and GCP, or other third-party organizations not performing data collection and analysis in a timely or accurate manner;
- service providers, collaborators or co-sponsors not adequately performing their obligations in relation to the clinical trial or cause the trial to be delayed or terminated;
- being unable to obtain a sufficient supply of manufactured clinical trial materials;
- regulatory inspections of manufacturing facilities requiring us or a co-sponsor to undertake corrective action or suspend the clinical trials;
- interim results of the clinical trial being inconclusive or negative;

- clinical trials, although approved and completed, generating data that are not considered by the FDA or other health regulatory agencies to be sufficient to demonstrate safety and efficacy;

- clinical trials, although approved and completed outside the United States, not considered by the FDA or others outside the jurisdiction hosting such clinical trials to be sufficient to demonstrate safety and efficacy; and

- changes in governmental regulations or administrative actions affecting the conduct of the clinical trial or the interpretation of its results.

There can be no assurance that our clinical trials will in fact demonstrate, to the satisfaction of the FDA and others, that our product candidates are sufficiently safe or effective. The FDA or we may also restrict or suspend our clinical trials at any time if either believes that we are exposing the subjects participating in the trials to unacceptable health risks.

Delays in obtaining such clearances and/or changes in existing requirements could have a material adverse effect on our company by making it difficult to advance product candidates or by reducing or eliminating their potential or perceived value and, therefore, our ability to conduct our business as currently planned could materially suffer. Failure to obtain required regulatory approvals could require us to delay, curtail or cease our operations. Even if we invest the necessary time, money and resources required to advance through the FDA approval process, there is no guarantee that we will receive FDA approval of our product candidates.

Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or other regulatory health agencies, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;

- repairs, replacements, refunds, recalls, or seizures of our products;

- operating restrictions, partial suspension, or total shutdown of production;

- refusing our requests for regulatory clearance or premarket approval of new products, new intended uses, or modifications to existing products;

- withdrawing regulatory clearance or premarket approvals that have already been granted; and

- criminal prosecution.

If any of these events were to occur, it could adversely affect our business, financial condition and results of operations.

**Even if we obtain regulatory approvals, our products will be subject to ongoing regulatory review and if we fail to comply with continuing regulations, we could lose those approvals and our business, financial condition and results of operations would be seriously harmed.**

Even if our product candidates receive initial regulatory approval or clearance for specific therapeutic applications, we will still be subject to ongoing reporting obligations, and such product and the related manufacturing operations will be subject to continuing regulatory review, including FDA and other health regulatory inspections. This ongoing review may result in the withdrawal of our product from the market, the interruption of manufacturing operations and/or the imposition of labeling and/or marketing limitations related to specific applications of our product. Since many more patients will be exposed to our product candidates following their marketing approval, serious but infrequent adverse events that were not observed in clinical trials may be observed during the commercial marketing of such product. In addition, the manufacturer(s) and the manufacturing facilities that we will use to produce our product candidates will be subject to periodic review and inspection by the FDA and other health regulatory agencies. Late discovery of previously unknown problems with any product, manufacturer or manufacturing process, or failure to comply with regulatory requirements, may result in actions, such as:

- restrictions on such product, manufacturer or manufacturing process;

- warning letters from the FDA or other regulatory authorities;

- withdrawal of the product from the market;
- suspension or withdrawal of regulatory approvals;
- refusal by such regulator to approve pending applications or supplements to approved applications that we or our licensees (if any) submit;
- voluntary or mandatory recall;
- fines;
- refusal to permit the import or export of our product;
- product seizures or detentions;
- injunctions or the imposition of civil or criminal penalties; and
- adverse publicity.

In addition, from time to time, legislation is drafted and introduced in the United States that could significantly change the statutory provisions governing any regulatory clearance or approval that we receive from the U.S. regulatory authorities. FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our product. We cannot predict what these changes will be, how or when they will occur or what effect they will have on the regulation of our product. If we, or our licensees, suppliers, collaborative research partners or clinical investigators are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or the adoption of new regulatory requirements or policies, we may lose marketing approval for any of the therapeutic applications of our product (to the extent that such applications are initially approved), resulting in decreased or lost revenue from milestones, product rental or usage fees, or royalties.

Off-label use is common in the indications for which our product candidates are under development, which may result in enforcement actions by the FDA and other regulatory health agencies for violations of the laws and regulations prohibiting the promotion of off-label uses.

Although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications, pharmaceutical companies are prohibited from marketing or promoting their drug products for uses outside the approved label, a practice known as off-label promotion. Certain of our product candidates, including AEVI -001 and AEVI -002, are under development for indications for which off-label use is common. To the extent the price of our product candidates, if approved, is significantly higher than the prices of commercially available products that are frequently prescribed off-label, physicians may recommend and prescribe these commercial alternatives instead of writing prescriptions for our products. Either of these outcomes may adversely impact our results of operations by limiting how we price our product and increasing our competition.

In addition, if any of our product candidates are approved, our product labeling, advertising and promotional materials would be subject to regulatory requirements and continuing review by the FDA, Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. If we are found to have improperly promoted off-label uses of our product candidates, if approved, we may become subject to significant liability. Such enforcement has become more common in the industry. If we are found to have promoted our products for any such off-label uses, the federal government could levy civil, criminal or administrative penalties, and seek fines against us. The FDA or other regulatory authorities could also request that we enter into a consent decree or a corporate integrity agreement, or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

In the United States, engaging in the impermissible promotion of our products, following approval, for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute drug products through, for example, corporate integrity agreements, and debarment, suspension or exclusion from participation in federal and state healthcare programs. These false claims statutes include, among others, federal civil False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing others to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. These false claims lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices promoting off-label drug uses. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, if any, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have an adverse effect on our business, financial condition, results of operations and prospects.

**Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.**

Even if the FDA or any other regulatory health agency approves the marketing of any product candidates that we develop, physicians, patients, third-party payors or the medical community may not accept or use them. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If AEVI-001, AEVI -002 or any future product candidate that we develop does not achieve an adequate level of acceptance, we may not generate significant product revenue or any profits from operations. The degree of market acceptance of AEVI-001, AEVI -002 or any of our future product candidates that are approved for commercial sale will depend on a variety of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- our ability to offer our products, if approved, for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement, and patients' willingness to pay out-of-pocket in the absence of third-party coverage or adequate reimbursement;
- the prevalence and severity of any side effects;
- any restrictions on the use of our products, if approved, together with other medications; and
- other potential advantages over alternative treatment methods.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our products, if approved, may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates. Because we expect sales of our product candidates, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business and could require us to seek additional financing.

**Our efforts to comply with federal and state fraud and abuse laws could be costly, and, if we are unable to fully comply with such laws, we could face substantial penalties.**

We are subject to extensive federal and state healthcare fraud and abuse laws and regulations, including, but not limited to, the following:

- federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs, such as Medicare and Medicaid;

- federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which creates federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program and which also imposes certain obligations on entities with respect to the privacy, security and transmission of individually identifiable health information;

- federal False Statements Statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- federal Foreign Corrupt Practices Act (FCPA), which prohibits, among other things, making payments to foreign officials of any country outside of the United States for the purpose of obtaining or retaining business; and

- state laws analogous to each of the above federal laws, such as state anti-kickback and false claims laws (some of which may apply to healthcare items or services reimbursed by any third-party payer, including commercial insurers), as well as certain state laws that require pharmaceutical and medical device companies to comply with industry voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government.

If our past or present operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from third-party payer programs such as Medicare and Medicaid and/or the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we may do business are found to be non-compliant with applicable laws, they may be subject to criminal, civil or administrative sanctions including exclusions from government-funded health care programs, which could also negatively impact our operations. Our ongoing efforts to comply with these laws may be costly, and our failure to comply with these laws could have a material adverse effect on our business, financial condition and results of operations. The risk of our being found in violation of these laws is increased by the fact that many of them have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations. In addition, these laws and their interpretations are subject to change. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

**Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.**

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

**We expect to rely on third-party contractors and organizations to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.**

We rely and expect to continue to rely on third-party third-party contractors, clinical data management organizations, independent contractors, medical institutions and clinical investigators to conduct our clinical trials of AEVI-001 and AEVI-002, and for our other programs. These agreements may terminate for a variety of reasons, including a failure to perform by the third parties. If we needed to enter into alternative arrangements, our product development activities could be delayed.

We compete with many other companies, some of which may be our competitors, for the resources of these third parties. Large pharmaceutical companies often have significantly more extensive agreements and relationships with such third-party providers, and such third-party providers may prioritize the requirements of such large pharmaceutical companies over ours. The third parties on whom we rely may terminate their engagements with us at any time, which may cause delay in the development and commercialization of our product candidates. If any such third party terminates its engagement with us or fails to perform as agreed, we may be required to enter into alternative arrangements, which would result in significant cost and delay to our product development program. Moreover, our agreements with such third parties generally do not provide assurances regarding employee turnover and availability, which may cause interruptions in the research on our product candidates by such third parties.

Our reliance on these third parties to conduct our clinical trials will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and other regulatory authorities require us to comply with standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We are also required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

**If any of our key employees discontinue his or her services with us, our efforts to develop our business may be delayed.**

Our success will depend on the retention of our directors and other current and future members of our management and technical team, including Michael F. Cola, our President and Chief Executive Officer, Brian D. Piper, our Chief Financial Officer, and Garry A. Neil, our Chief Scientific Officer, and on our ability to continue to attract and retain highly skilled and qualified personnel. There can be no assurance that we will retain the services of any of our directors, officers or employees, or attract or retain additional senior managers or skilled employees. Furthermore, we do not carry key man insurance with respect to any of such individuals.

Our lead product candidates, including AEVI-001 and AEVI-002, are still in development and are dependent on further development and testing. We currently employ a small number of key personnel including top managers, scientists, engineers and clinical experts who are important to developing AEVI-001 and AEVI-002 and have a high level of accumulated knowledge which would be lost if they left our Company. If these employees leave our Company or otherwise are unable to provide services, there could be significant implications on the timing and cost of future development of the technology. Because competition for qualified personnel in our industry is intense, we may be unable to timely find suitable replacements with the necessary scientific expertise. We cannot assure you that our efforts to attract or retain such personnel will be successful.

**We are subject to intense competition from companies with greater resources and more mature products, which may result in our competitors developing or commercializing products before or more successfully than us.**

While we believe our product candidates have significant advantages, there are a number of well-established and sizeable companies engaged in the development, production, marketing, sale and distribution of products and product candidates that may potentially be competitive with our product candidates. Many of these companies are more experienced than our company and represent significant competition. It is also possible that other parties have in development product candidates substantially similar to or with properties that are more efficacious, less invasive and more cost effectively delivered than our product candidates. The success of our competitors in developing, bringing to market, selling and distributing their products could negatively affect our result of operations and/or general acceptance of our product candidates.

**We face risks related to the general economic conditions that may adversely affect our business.**

In general, our operating results can be significantly and adversely affected by negative economic conditions, high labor, material and commodity costs, and unforeseen changes in demand for our potential products. These conditions have resulted and could continue to result in slower adoption of new technologies and cost containment efforts by governments and other payers for healthcare research and development, products and services.

**Health care policy changes may have a material adverse effect on us.**

Health care reform is often a subject of attention in governments that are trying to control health care expenditures. Health care reform proposals have been the subject of much debate in the U.S. Congress and some state legislatures, as well as in other countries. There is no assurance that legislation or underlying rules and guidelines resulting in adverse effects on our company or our product candidates will not be adopted in a country in which we intend to operate and/or upon the distribution of our product candidates in the United States.

In March 2010, President Obama signed into law the ACA and the Health Care and Education Reconciliation Act of 2010. The legislation imposes significant new taxes on medical device makers in the form of a 2.3% excise tax on all U.S. medical device sales that began January 1, 2013. The FDA classifies IVD companion diagnostics as medical devices. Under the law, the total cost to the medical device industry from the tax is expected to be approximately $29 billion over ten years. This significant increase in the tax burden on our industry could have a material, negative impact on our results of operations and our cash flows, especially if any of our product candidates were determined to be a medical device. Other elements of this legislation, such as comparative effectiveness research, an independent payment advisory board, payment system reforms, including shared savings pilots, and other provisions, could meaningfully change the way health care is developed and delivered, and may materially impact numerous aspects of our business. Finally, there are ongoing efforts to modify or eliminate the ACA. It is unknown what form any such modifications or any law proposed to replace the ACA would take, and how or whether it may affect our business in the future.

In August 2017, President Trump signed into law the Food & Drug Administration Reauthorization Act (FDARA). This legislation imposes significant new requirements for clinical trial sponsors which will affect, among other things, obtaining orphan drug designation, and the development of drugs and biological products for pediatric use. This legislation will result in new regulations which might materially impact our business.

**Reimbursement policies of third-party payers may negatively affect the acceptance of our product candidates by subjecting the product candidates to sales and pharmaceutical pricing controls.**

Third-party payers (Medicare, Medicaid, private health insurance companies and other organizations) may affect the pricing or relative attractiveness of our product candidates by regulating the level of reimbursement provided to the physicians and clinics utilizing our product candidates or by refusing reimbursement. If reimbursement under these programs, or if the amount of time to secure reimbursement is too long, our ability to market our technology and product candidates may be adversely and materially affected. In international markets, reimbursement by private third-party medical insurance providers, including government insurers and independent providers, varies from country to country. In certain countries, our ability to achieve significant market penetration may depend upon the availability of third-party government reimbursement. Pharmaceutical pricing is also subject to regulation in other countries within which we may wish to distribute our product candidates.

The ACA reduces Medicare and Medicaid payments to hospitals, clinical laboratories and pharmaceutical companies, and could otherwise reduce the volume of medical procedures. Further, the Budget Control Act enacted in August 2011 committed the U.S. federal government to significantly reduce the federal deficit over ten years. In addition to placing caps on discretionary spending through 2021, the Budget Control Act also established a budget sequestration that calls for automatic spending cuts over a nine-year period. Across-the-board spending cuts went into effect on March 1, 2013, and Medicare spending cuts that reduce Part A and Part B payments by 2% went into effect on April 1, 2013. Further, the Bipartisan Budget Act of 2013, passed in December 2013, extends the sequestration automatic Medicare spending cuts to 2023 from 2021. Although we cannot predict the full effect on our business of the implementation of existing legislation such as the ACA and the Budget Control Act, or the enactment of additional legislation, we believe that legislation or regulation that reduces reimbursement for our products could adversely affect how much or under what circumstances health care providers will prescribe or administer our products. This could materially and adversely impact our business by reducing our ability to generate revenue, raise capital, obtain additional collaborators and market our products. In addition, we believe the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of pharmaceutical products, which may adversely impact product sales.

The pricing of pharmaceutical products, in general, and specialty drugs, in particular, has also been a topic of concern in the U.S. government. There can be no assurance as to how this scrutiny on pricing of pharmaceutical products will impact future pricing of our products or orphan drugs or pharmaceutical products generally.

**We may experience product liability claims, which could adversely affect our business and financial condition.**

We may become subject to product liability claims. We have not experienced any product liability claims to date; however, the production at commercial scale, distribution, sale and support of our product candidates may entail the risk of such claims, which is likely to be substantial in light of the use of our product candidates in the treatment of medical conditions. We carry product liability insurance coverage in connection with the clinical trials of our product candidates. If we are unable to obtain a renewal or if we suffer a successful product liability claim in excess of our insurance coverage, such claim could result in significant monetary liability and could have a material adverse impact on our business, operations, financial position and/or reputation.

**Failure to maintain effective internal controls could have a material adverse effect on our business and operating results. In addition, current and potential stockholders could lose confidence in our financial reporting, which could have a material adverse effect on the price of our common stock.**

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our results of operation could be harmed.

Section 404 of the Sarbanes-Oxley Act of 2002 requires annual management assessments of the effectiveness of our internal controls over financial reporting and a report by our independent registered public accounting firm addressing these assessments. We continuously monitor our existing internal controls over financial reporting systems to confirm that they are effective, and we may identify deficiencies that we may not be able to remediate in time to meet the deadlines imposed by the Sarbanes-Oxley Act. This process may divert internal resources and will take a significant amount of time and effort to complete.

If at any time it is determined that our internal controls are not effective, we may be required to implement new internal control procedures and reevaluate our financial reporting. We may experience higher than anticipated operating expenses as well as increased independent auditor fees during the implementation of these changes and thereafter. Further, we may need to hire additional qualified personnel. If we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act, which could result in our being unable to obtain an unqualified report on internal controls from our independent auditors. Failure to maintain an effective internal control environment could also cause investors to lose confidence in our reported financial information, which could have a material adverse effect on the price of our common stock.

**Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses, divert management's attention from operating our business which could have a material adverse effect on our business.**

There have been changing laws, regulations and standards relating to corporate governance and public disclosure, as well as new regulations promulgated by the SEC and rules promulgated by the national securities exchanges, including the Nasdaq Global Market. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. As a result, our efforts to comply with evolving laws, regulations and standards are likely to continue to result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. Our board members, principal executive officer and principal financial officer could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may have difficulty attracting and retaining qualified board members and executive officers, which could have a material adverse effect on our business. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies, we may incur additional expenses to comply with standards set by regulatory authorities or governing bodies which would have a material adverse effect on our business, financial condition and results of operations.

**Security breaches and other disruptions to our information technology infrastructure could interfere with our operations or clinical trials, compromise information belonging to us and our suppliers and expose us to liability, which could adversely impact our business and reputation.**

In the ordinary course of business, we rely on information technology networks and systems, some of which are managed by third parties, to process, transmit and store electronic information, and to manage or support a variety of business processes and activities, including the conduct of our clinical trials. Additionally, we collect and store sensitive data, including proprietary business information and confidential patient health information. Despite security measures and business continuity plans, our information technology networks and infrastructure may be vulnerable to damage, disruptions or shutdowns due to attack by hackers or breaches, employee error or malfeasance, power outages, computer viruses, telecommunication or utility failures, systems failures, natural disasters or other catastrophic events. Any such event could result in legal claims or proceedings, liability or significant penalties under privacy laws, disruption in operations and damage to our reputation, which could adversely affect our business.

**The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.**

On December 22, 2017, President Trump signed into law the final version of the tax reform bill commonly known as the "Tax Cuts and Jobs Act," or the TCJA, that significantly reforms the Internal Revenue Code of 1986, as amended, with many of its provisions effective for tax years beginning on or after January 1, 2018. The TCJA, among other things, contains significant changes to corporate taxation, including a permanent reduction of the corporate income tax rate, a partial limitation on the deductibility of business interest expense, a limitation of the deduction for net operating loss carryforwards to 80% of current year taxable income, an indefinite net operating loss carryforward and the elimination of the two-year net operating loss carryback, temporary, immediate expensing for certain new investments , and the modification or repeal of many business deductions and credits. We continue to examine the impact this tax reform legislation may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the TCJA is uncertain and our business and financial condition could be adversely affected. The impact of this reform on our stockholders is uncertain. Stockholders should consult with their tax advisors regarding the effect of the TCJA and other potential changes to the U.S. Federal tax laws on them.

**Risks Related to Our Intellectual Property**

**If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize product candidates similar or identical to ours, and our ability to successfully commercialize our product candidates may be impaired.**

As is the case with other biopharmaceutical companies, our success depends in large part on our ability to obtain and maintain protection of the intellectual property we may own solely and jointly with others, particularly patents, in the United States and other countries with respect to our product candidates and technology. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to AEVI-001, AEVI-002, or other product candidates that we may identify.

Obtaining and enforcing biopharmaceutical patents is costly, time consuming and complex, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal, technological and factual questions and has in recent years been the subject of much litigation. Applications for patents and other intellectual property rights capable of being registered have been, and will be, filed in certain key jurisdictions. We may not successfully obtain patents in the countries in which patent applications have been or will be filed, and we may not develop other patentable products or processes. In addition, the patents we own and license, or any further patents we may own or license, may not prevent other persons or companies from developing similar or therapeutically equivalent products, and other persons or companies may be issued patents that may prevent the sale of our products or that will require us to license or pay significant fees or royalties. Patents also will not protect our product candidates if competitors devise ways of making or using these product candidates without legally infringing our patents. Furthermore, our own issued and in-licensed patents may not be valid or enforceable or be able to provide our company with meaningful protection. In recent years, several companies have been extremely aggressive in challenging patents covering pharmaceutical products, and the challenges have often been successful. We cannot be assured that our patents will not be challenged by third parties or that we will be successful in any defense we undertake. Patent litigation is costly and time-consuming, and there can be no assurance that we will have, or will be able to devote, sufficient resources to pursue such litigation. In addition, potentially unfavorable outcomes in such proceedings could limit our intellectual property rights and activities and have an adverse effect on our business.

In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, we may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office, or the USPTO. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive product candidates. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative product candidates in a non-infringing manner.

In addition, even if patents do issue to us or our licensors covering embodiments of our product candidates, devices, or methods of using them, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and those patents can be challenged by our competitors or other third parties in the courts or patent offices in the United States and abroad. For example, we may become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical product candidates, or limit the duration of the patent protection of our product candidates. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

**If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or these agreements are terminated or we otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.**

We are party to several license agreements under which we in-license patent rights and other intellectual property related to our business. For example, we are party to a license agreement with CHOP, under which we license certain technology owned and controlled by CHOP related to ADHD and certain other neurological and neuropsychological indications. Pursuant to this license agreement, CHOP licensed to neuroFix (coupled with a right to sublicense) certain patent rights and compound know-how on an exclusive, worldwide, royalty-bearing right and license basis, and certain CHOP know-how (other than compound know-how) on a non-exclusive, worldwide, royalty-bearing right and license basis. We are also party to a Development and Option Agreement with KHK under which we may license certain technology related AEVI-002. We may need to obtain additional licenses from others in the future to advance our research and development activities or allow the commercialization of AEVI-001, AEVI-002, or any other product candidates we may identify and pursue. See the section entitled “Business” for a more detailed description of our current license agreements.

Our license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. Any uncured, material breach under these license agreements could result in our loss of rights to practice the patent rights and other intellectual property licensed to us under these agreements, and could compromise our development and commercialization efforts for AEVI-001 and AEVI-002, or any future product candidates. If any of our current or future licenses or material relationships or any in-licenses upon which our current or future licenses are based are terminated, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to AEVI-001 and AEVI-002 and we may be required to cease our development and commercialization of AEVI-001 and AEVI-002, or any future product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

If any of our current or future licenses or material relationships or any in-licenses upon which our current or future licenses are based are terminated or breached, we may:

- lose our rights to develop and market AEVI-001, AEVI-002 or any future product candidates;
- lose patent protection for AEVI-001, AEVI-002 or any future product candidates;
- experience significant delays in the development or commercialization of AEVI-001, AEVI-002 or any future product candidates;
- not be able to obtain any other licenses on acceptable terms, if at all; or
- incur liability for damages.

If we experience any of the foregoing, it could harm our business, financial condition and results of operations.

**Our intellectual property in-licenses with third parties may be subject to disagreements over contract interpretations, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.**

The agreements under which we currently in-license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

As we develop our product candidates, we may need to obtain additional licenses to protect our rights to make and use our technology. These licenses may not be available on acceptable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. All of the issues described above could also impact our collaborators, which would also impact the success of the collaboration and therefore us. Under certain of our in-licensed patents, the licensor is responsible for maintaining, controlling or enforcing the licensed intellectual property portfolio. Thus, we cannot ensure that the patent rights licensed to us will be adequately maintained, controlled or enforced by our licensor. In addition, even when we have the right to control patent prosecution of licensed patents and patent applications, enforcement of licensed patents, or defense of claims asserting the invalidity of those patents, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to or after our assuming control.

**We may be required to make significant payments in connection with our license and development agreements.**

We are party to license agreements with CHOP and a Development and Option Agreement with KHK pursuant to which we exclusively license certain technology related to the development of AEVI-001 and AEVI-002. Under our license agreements with CHOP, we may be required to make significant payments in connection with the achievement of certain milestones and royalties on the sale of resulting products. If we exercise our option under the terms of KHK Development and Option Agreement, we will be obligated to cover significant development costs for AEVI-002 and make significant payments in connection with certain milestones and the sale of resulting products. If these obligations become due under the terms of the CHOP license agreements or the Development and Option Agreement, we may not have sufficient funds available to meet our obligations and our development efforts may be negatively impacted.

**Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.**

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and *inter partes* reexamination proceedings before the USPTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that AEVI-001, AEVI-002, or other product candidates that we may identify may be subject to claims of infringement of the patent rights of third parties.

Third parties may bring patent infringement or other intellectual property claims against us, which would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of AEVI-001, AEVI-002, or other product candidates that we may identify. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that AEVI-001, AEVI-002 or other product candidates that we may identify may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of AEVI-001, AEVI-002, or other product candidates that we may identify, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire.

Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all, or it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize AEVI-001, AEVI-002, or other product candidates that we may identify. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

If a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product candidate that is the subject of the suit. Additionally, if it is determined that our product candidates infringe third-party patents or other intellectual property rights, there can be no assurance that we can successfully develop non-infringing alternatives on a timely basis or license non-infringing alternatives, if any exist, on commercially reasonable terms. A significant intellectual property impediment to our ability to develop and commercialize our product candidates could materially adversely affect our business prospects.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

**Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.**

Even if our product candidates and the methods for treating patients for prescribed indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope, disclosure, and support in the specification, the patents will provide protection only for a limited amount of time. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

**If we are not able to obtain patent term extension or non-patent exclusivity in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for AEVI-001, AEVI-002, or other product candidates that we may identify, our business may be materially harmed.**

Depending upon the timing, duration and specifics of FDA marketing approval of AEVI-001, AEVI-002, or other product candidates that we may identify, one of the U.S. patents covering each of such product candidates or the use or manufacturing method thereof may be eligible for up to five years of patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates. Nevertheless, we may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product may be shortened and our competitors may obtain approval of competing products following our patent expiration sooner, and our revenue could be reduced, possibly materially.

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a U.S. patent covering AEVI-001, AEVI-002 or other product candidates that we may identify even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought. Further, for certain of our licensed patents, we do not have the right to control prosecution, including filing with the USPTO, a petition for patent term extension under the Hatch-Waxman Act. Thus, if one of our licensed patents is eligible for patent term extension under the Hatch-Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the USPTO.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of such product candidate.

**If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.**

Our business is dependent on proprietary rights that may be difficult to protect and such dependence could affect our ability to effectively compete. In addition to patents, we also rely on trade secrets, technical know-how, licensing opportunities, and continuing innovation to develop and maintain our competitive position especially where we do not believe that patent protection is appropriate or obtainable. Trade secrets are by nature difficult to protect. We seek to protect our proprietary information by requiring our employees, consultants, contractors, outside scientific collaborators and other advisors to execute non-disclosure and confidentiality agreements and our employees to execute assignment of invention agreements to us. We also require confidentiality or material transfer agreements from third parties that receive our confidential data or materials. These agreements are designed to protect our proprietary information. However, we cannot be certain that such agreements have been entered into with all relevant parties, and even if they are all in place, there can still be no guarantee that agreements have not been or will not be violated or that there will be an adequate remedy available for a violation of an agreement. Accordingly, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, if our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time-consuming, and the outcome is unpredictable. Moreover, others, including our competitors, may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or technology.

We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

We anticipate that we will spend both time and management resources to develop and file trademark applications in the future. However, third parties may have trademarks or pending trademark applications on our contemplated marks, similar marks, or in confusingly similar fields of use (or may be using our contemplated marks or similar marks). We may have to change our use of certain marks which could have an adverse impact on our business and may require us to spend additional funds to develop new marks.

**Although we are not currently involved in any intellectual property litigation, we may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.**

Unauthorized parties may infringe our patents or other intellectual property, try to copy aspects of our product candidates and technologies, or obtain and use information we consider proprietary. Policing the unauthorized use of our proprietary rights is difficult. We cannot guarantee that no harm or threat will be made to our or our collaborators' intellectual property. In addition, changes in, or different interpretations of, patent laws in the United States and other countries may also adversely affect the scope of our patent protection and our competitive situation. Further, we may not have sufficient rights under our license agreements with collaborators to enforce the intellectual property licensed to us against third-party infringers.

Although we are not currently involved in any litigation, if we were to initiate legal proceedings against a third party to enforce a patent covering AEVI-001, AEVI-002, or other product candidates that we may identify, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring AEVI-001, AEVI-002, or other product candidates that we may identify to market. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

**We may be subject to claims challenging the inventorship of our patents and other intellectual property.**

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

**Any issued patents that may cover our product candidates could be found invalid or unenforceable if challenged in court.**

Third parties may claim that our owned or in-licensed patents relating to AEVI-001, AEVI-002, or other product candidates that we may identify, are invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover AEVI-001, AEVI-002, or other product candidates that we may identify. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

**We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.**

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Agreements with our employees aim to prevent employees from bringing any proprietary rights of third parties to us. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

**Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.**

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside agency and rely on our outside agency to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

**We may not be able to protect our intellectual property rights throughout the world.**

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. For example, there is certain subject matter that is patent eligible in the United States but not generally patent eligible outside of the United States and vice versa. Differences in what constitutes patent eligible subject matter in various countries may limit the protection we can obtain in the United States and outside of the United States. Furthermore, different countries have different procedures for obtaining patents, and patents issued in different countries provide different degrees of protection against the use of a patented invention by others. Therefore, if the issuance to us or our licensors, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement in, a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited.

Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

**Changes in U.S. and foreign patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.**

Changes in either the patent laws or interpretation of the patent laws in the United States and abroad could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For example, assuming that other requirements for patentability are met, prior to March 2013, in the United States, in general, the first to invent was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

**Risk Related to our Securities**

**Our securities are thinly traded, resulting in relative illiquidity and price volatility, and there may not ever be an active market for our securities.**

Although our common stock has been traded on the Nasdaq Global Market since October 21, 2016 and, prior to that on the NYSE MKT since April 8, 2011, the volumes and trading in our securities have been extremely sporadic. As a result, the ability of holders to purchase or sell our securities is limited, with low-volume trading creating wide shifts in price. For our securities to continue to be listed on the Nasdaq Global Market, we must meet the current listing requirements of that exchange. If we were unable to meet these requirements, our securities could be delisted from the Nasdaq Global Market. Any such delisting of our securities could have an adverse effect on the market price of, and the efficiency of the trading market for, our securities, not only in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and less coverage of us by securities analysts, if any. Also, if in the future we were to determine that we need to seek additional equity capital, it could have an adverse effect on our ability to raise capital in the public or private equity markets.

Further, the share prices of public companies, particularly those operating in high growth sectors, are often subject to significant fluctuations. The market price of our common stock on the Nasdaq Global Market has been volatile, ranging from $1.01 per share to $2.65 per share during the 52-week trading period ending June 30, 2018. We expect that the market price of our common stock will continue to fluctuate significantly due to factors including, but not limited to, the following:

- results of our clinical trials, such as the Phase 2 trial in mGluR+ Genetic Subset ADHD to confirm genetic responders to AEVI-001, for which data is expected in the fourth quarter of 2018 and the 8-week signal finding study of AEVI-002 in patients with severe pediatric onset Crohn's disease, for which initial data from a small number of patients is expected by year-end 2018,
- announcements of developments by us or our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- adoption of new accounting standards affecting our industry;
- introduction of new products by us or our competitors;
- changes in market valuations of companies in our industry;
- actual or anticipated variations in our operating results;
- future issuances of our common stock or other securities;
- other events or factors, including those beyond our control; and
- general market or economic conditions.

**Securities analysts may not initiate coverage or continue to cover our common stock, and this may have a negative impact on its market price.**

The trading market for our securities could depend in part on the research and reports that securities analysts publish about our business and us. We do not have any control over these analysts. There is no guarantee that securities analysts will cover our securities. If securities analysts do not cover our securities, the lack of research coverage may adversely affect their market prices. If we are covered by securities analysts, and our securities are the subject of an unfavorable report, the prices for our securities would likely decline. If one or more of these analysts ceases to cover us or fails to publish regular reports on us, we could lose visibility in the financial markets, which could cause our stock price and/or trading volume to decline.

**The exercise of options and other issuances of shares of common stock or securities convertible into or exercisable for shares of common stock will dilute the ownership interests of our current stockholders and may adversely affect the future market price of our common stock.**

Sales of our common stock in the public market, either by us or by our current stockholders, or the perception that these sales could occur, could cause a decline in the market price of our securities. Nearly all of the shares of our common stock held by those of our current stockholders who are not affiliates may be immediately eligible for resale in the open market either in compliance with an exemption under Rule 144 promulgated under the Securities Act of 1933, as amended, or the Securities Act, or pursuant to an effective resale registration statement that we have previously filed with the SEC. Such sales, along with any other market transactions, could adversely affect the market price of our common stock.

In addition, as of June 30, 2018, there were outstanding options and warrants to purchase an aggregate of 10,749,651 and 3,953,904 shares, respectively. Of the 10,749,651 outstanding options, ranging in exercise price from $1.07 per share to $8.80 per share, 6,344,864 shares were exercisable as of June 30, 2018. The exercise of options at prices below the market price of our common stock could adversely affect the price of shares of our common stock. Additional dilution may result from the issuance of shares of our common stock in connection with collaborations or manufacturing arrangements or in connection with other financing efforts.

Any issuance of our common stock that is not made solely to then-existing stockholders proportionate to their interests, such as in the case of a stock dividend or stock split, will result in dilution to each stockholder by reducing his, her or its percentage ownership of the total outstanding shares. Moreover, if we issue options or warrants to purchase our common stock in the future and those options or warrants are exercised, stockholders may experience further dilution. Delaware law and our corporate governance documents do not prohibit the number of options or other securities that are convertible into, exchangeable for or represent the right to receive common stock that we may issue in the future, except to the extent we are limited by the number of our authorized shares of common stock which is currently 200,000,000 shares. Holders of shares of our common stock have no preemptive rights that entitle them to purchase their pro rata share of any offering of shares of any class or series.

**We have a significant stockholder, which will limit your ability to influence corporate matters and may give rise to conflicts of interest.**

The Children's Hospital of Philadelphia Foundation (the "CHOP Foundation") is our largest stockholder. As of June 30, 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. Accordingly, the CHOP Foundation exerts significant influence over us and any action requiring the approval of the holders of our common stock, including the election of directors and approval of significant corporate transactions. This concentration of voting power makes it less likely that any other holder of common stock or directors of our business will be able to affect the way we are managed and could delay or prevent an acquisition of us on terms that other stockholders may desire. In addition, if the CHOP Foundation obtains a majority of our common stock, the CHOP Foundation would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, the CHOP Foundation would be able to control the election of directors, amendments to our organizational documents and approval of any merger, consolidation, sale of all or substantially all of our assets or other business combination or reorganization. In addition, if the CHOP Foundation obtains a majority of our common stock, we would be deemed a "controlled company" for purposes of NASDAQ listing requirements. Under NASDAQ rules, a "controlled company" may elect not to comply with certain NASDAQ corporate governance requirements, including (i) the requirement that a majority of our board of directors consist of independent directors, (ii) the requirement that the compensation of our officers be determined or recommended to the board by a majority of independent directors or a compensation committee that is composed entirely of independent directors and (iii) the requirement that director nominees be selected or recommended to the board by a majority of independent directors or a nominating committee that is composed of entirely independent directors.

Furthermore, the interests of the CHOP Foundation may not always coincide with your interests or the interests of other stockholders and the CHOP Foundation may act in a manner that advances its best interests and not necessarily those of other stockholders, including seeking a premium value for its common stock, and might affect the prevailing market price for our common stock. Our board of directors, which currently consists of eight directors, including one designated by the CHOP Foundation, has the power to set the number of directors on our board from time to time. Matthew D. Bayley, who currently serves as the Senior Vice President and Chief Strategy Officer at the CHOP Foundation, is a member of our board of directors and some of its committees.

**If we fail to comply with the continued listing requirements of the Nasdaq Global Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.**

Our common stock is listed for trading on the Nasdaq Global Market. We must satisfy Nasdaq's continued listing requirements, including, among other things, a minimum closing bid price requirement of $1.00 per share for our common stock.

If a company trades for 30 consecutive business days below the $1.00 minimum closing bid price requirement, Nasdaq will send a deficiency notice to the company, advising that it has been afforded a "compliance period" of 180 calendar days to regain compliance with the applicable requirements. Thereafter, if such a company does not regain compliance with the bid price requirement, a second 180-day compliance period may be available. If Nasdaq does not grant such a company a second 180-day compliance period or such company does not regain compliance with the bid price requirement, such company may be delisted from the Nasdaq Global Market.

A delisting of our common stock from Nasdaq could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and fewer business development opportunities.

**We have never declared or paid dividends on our capital stock and we do not anticipate paying any cash dividends in the foreseeable future.**

We have never declared or paid dividends on our capital stock and we do not anticipate paying any cash dividends in the foreseeable future. We currently intend to retain future earnings, if any, to fund the development and growth of our business. Any future determination to pay dividends will be at the discretion of our Board of Directors and will be dependent upon our financial condition, operating results, capital requirements, applicable contractual restrictions and other such factors as our Board of Directors may deem relevant.

**Provisions of Delaware law may delay or prevent efforts to acquire a controlling interest in us, even if such acquisition were in the best interests of our stockholders.**

We are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock. These provisions may also prevent changes in our management.

**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**

None.

**ITEM 6. Exhibits**

| Exhibit No. | Description |
|---|---|
| 10.1 | Equity Distribution Agreement, dated May 15, 2018, by and between Aevi Genomic Medicine, Inc. and JMP Securities LLC (previously filed as Exhibit 1.1 to our Current Report on Form 8-K filed on May 15, 2018 and incorporated herein by reference). |
| 10.2 | Amendment No. 2 to Sponsored Research Agreement, dated as of February 16, 2017, by and between The Children's Hospital of Philadelphia and Medgenics Medical Israel, Ltd. |
| 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: August 2, 2018

**AEVI GENOMIC MEDICINE, INC.**

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

Date: August 2, 2018

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

**Exhibit 10.2**

**Amendment #2 to Sponsored Research Agreement**

This Amendment #2 to Sponsored Research Agreement (this "Amendment #2"), executed on November 12, 2014 ("Agreement"), is made and entered into as of February 16, 2017 ("Amendment #2 Effective Date"), by and between Medgenics Medical Israel, Ltd. ("SPONSOR") and The Children's Hospital of Philadelphia ("CHOP").

**RECITALS**

Whereas SPONSOR and CHOP desire to amend the Sponsored Research Agreement to extend the term of the Agreement and to increase the Budget of the Research Program.

Whereas any capitalized term not separately defined in this Amendment #2 shall have the meaning ascribed to it in the Agreement.

Now, therefore, in consideration of the mutual agreements, promises and covenants contained herein SPONSOR and CHOP hereby agree to amend the Sponsored Research Agreement as follows:

1. Section 3.1 of the Agreement is hereby replaced in its entirety with the following:

> "Term. The term of this AGREEMENT shall begin on the EFFECTIVE DATE and shall end on June 30, 2018. At SPONSOR's Option, the term of this AGREEMENT shall automatically be extended for additional one (1) year terms if SPONSOR gives written notice of extension by June 30, 2017, and each anniversary thereafter. For the avoidance of doubt, if SPONSOR does not give written notice of extension by the applicable June 30 deadline, then the AGREEMENT shall expire at the end of the then-current term (which would be the next June 30 to occur following the applicable June 30 deadline). By way of example, if SPONSOR gives written notice of extension by June 30, 2017, then the term of the AGREEMENT will be extended through June 30, 2019, and if SPONSOR does not give written notice of extension by June 30, 2017, the AGREEMENT will expire on June 30, 2018."

2. Invoice and Payment Schedule of Attachment B (Budget) as attached to Amendment #1 to Sponsored Research Agreement dated December 18, 2015, is hereby supplemented by Attachment B to this Amendment #2 and thus the statement of work and budget for Phase 3 is authorized through June 30, 2018. Unless the parties otherwise agree in writing, the Budget for each one (1) year extension will be $4,750,000, invoiced and paid in twelve (12) equal monthly installments during the relevant extension year.

All other terms and conditions of the Sponsored Research Agreement not amended herein shall remain in full force and effect.

In witness whereof, SPONSOR and CHOP have caused this Amendment #2 to be duly executed as of the Amendment #2 Effective Date.

MEDGENICS MEDICAL ISRAEL, LTD.

By: /s/ Michael Cola
Name: Michael Cola
Title: Chief Executive Officer
Date:

THE CHILDREN'S HOSPITAL OF PHILADELPHIA

By: /s/ Prema Sundaram
Name: Prema Sundaram
Title: Manager, Sponsored Projects
Date:

AGREED AND ACKNOWLEDGED

By: /s/ Hakon Hakonarson
Name: Hakon Hakonarson.MD
Title: Principal Investigator, Director, CAG
Date:

**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: August 2, 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: August 2, 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 June 30, 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: August 2, 2018

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

Date: August 2, 2018

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