UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended **September 30, 2020**

☐ 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**: 001-37606**

ANAVEX LIFE SCIENCES CORP.

(Exact name of registrant as specified in its charter)

Nevada	98-0608404
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
51 W 52nd Street, 7th Floor, New York, NY USA	10019
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code 1-844-689-3939

Securities registered under Section 12(b) of the Act:

Common Stock, $0.001 par value	AVXL	NASDAQ Stock Market LLC
Title of each class	Trading Symbol	Name of each exchange on which registered

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $0.001 par value
(Title of class)

Indicate by checkmark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

Indicate by checkmark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.

Yes ☐ No ☒

Indicate by checkmark whether the registrant has (1) 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 every Interactive Data File required to be submitted 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 checkmark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated Filer	☒	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 Act).

Yes ☐ No ☒

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter: $177,399,544 based on a price of $3.15 per share, being the closing price of the registrant's common stock on March 31, 2020.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date 66,962,957 issued and outstanding as of December 28, 2020.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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Forward Looking Statements.

This Annual Report on Form 10-K includes forward-looking statements. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our anticipated future clinical and regulatory milestone events, future financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. The words "believe," "may," "estimate," "continue," "anticipate," "intend," "expect" "should," "forecast," "could," "suggest," "plan" and similar expressions, as they relate to us, are intended to identify forward-looking statements. Such forward-looking statements include, without limitation, statements regarding:

- our ability to successfully conduct clinical and preclinical trials for our product candidates;
- our ability to raise additional capital on favorable terms and the impact of such activities on our stockholders and stock price;
- the impact of the COVID-19 outbreak and its effect on us;
- our ability to generate any revenue or to continue as a going concern;
- our ability to execute our research and development plan on time and on budget;
- our products ability to demonstrate efficacy or an acceptable safety profile of our product candidates;
- our ability to obtain the support of qualified scientific collaborators;
- our ability, whether alone or with commercial partners, to successfully commercialize any of our product candidates that may be approved for sale;
- our ability to identify and obtain additional product candidates;
- our reliance on third parties in non-clinical and clinical studies;
- our ability to defend against product liability claims;
- our ability to safeguard against security breaches;
- our ability to obtain and maintain sufficient intellectual property protection for our product candidates;
- our ability to comply with our intellectual property licensing agreements;
- our ability to defend against claims of intellectual property infringement;
- our ability to comply with the maintenance requirements of the government patent agencies;
- our ability to protect our intellectual property rights throughout the world;
- competition;
- the anticipated start dates, durations and completion dates of our ongoing and future clinical studies;
- the anticipated designs of our future clinical studies;
- our anticipated future regulatory submissions and our ability to receive regulatory approvals to develop and market our product candidates, including any orphan drug or fast track designations; and
- our anticipated future cash position.

We have based these forward-looking statements largely on our current expectations and projections about future events, including the responses we expect from the U.S. Food and Drug Administration, ("FDA"), and other regulatory authorities and financial trends that we believe may affect our financial condition, results of operations, business strategy, preclinical and clinical trials, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions including without limitation the risks described in "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K. These risks are not exhaustive. Other sections of this Annual Report on Form 10-K include additional factors which could adversely impact our business and financial performance. Moreover, we

operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable laws including the securities laws of the United States, we assume no obligation to update or supplement forward-looking statements.

As used in this Annual Report on Form 10-K, the terms “we,” “us,” “our,”, “Company” and “Anavex” mean Anavex Life Sciences Corp., unless the context clearly requires otherwise.

PART I

ITEM 1. BUSINESS

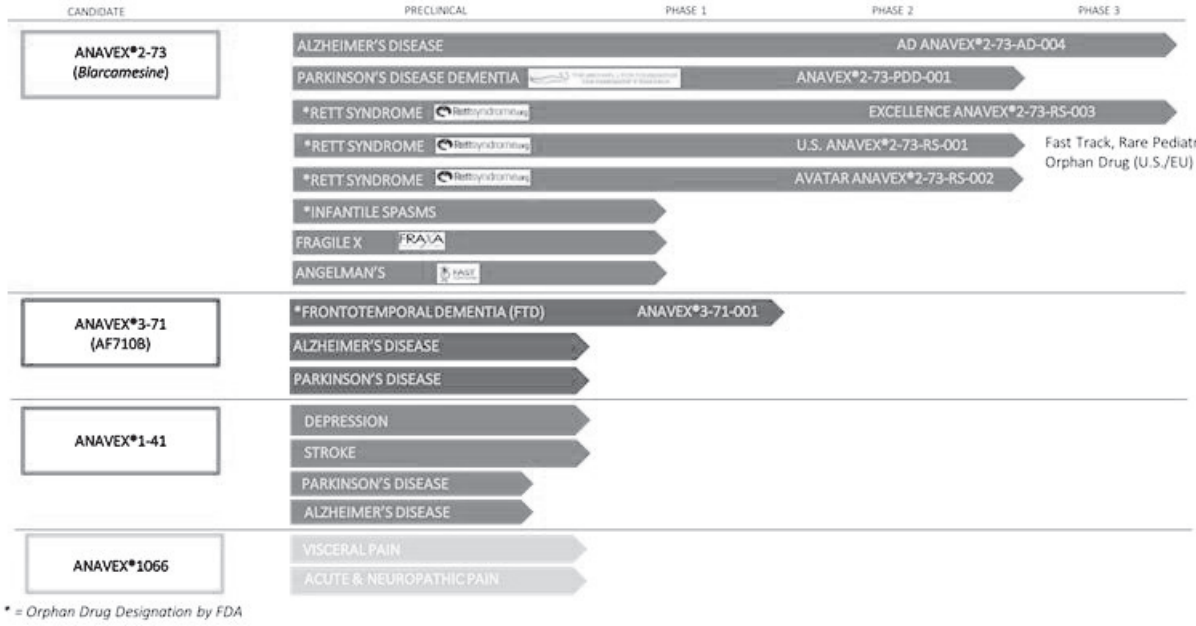
Overview and Strategy

Anavex Life Sciences Corp. is a clinical stage biopharmaceutical company engaged in the development of differentiated therapeutics by applying precision medicine to central nervous system ("CNS") diseases with high unmet need. We analyze genomic data from clinical studies to identify biomarkers, which we use to select patients that will receive the therapeutic benefit for the treatment of neurodegenerative and neurodevelopmental diseases.

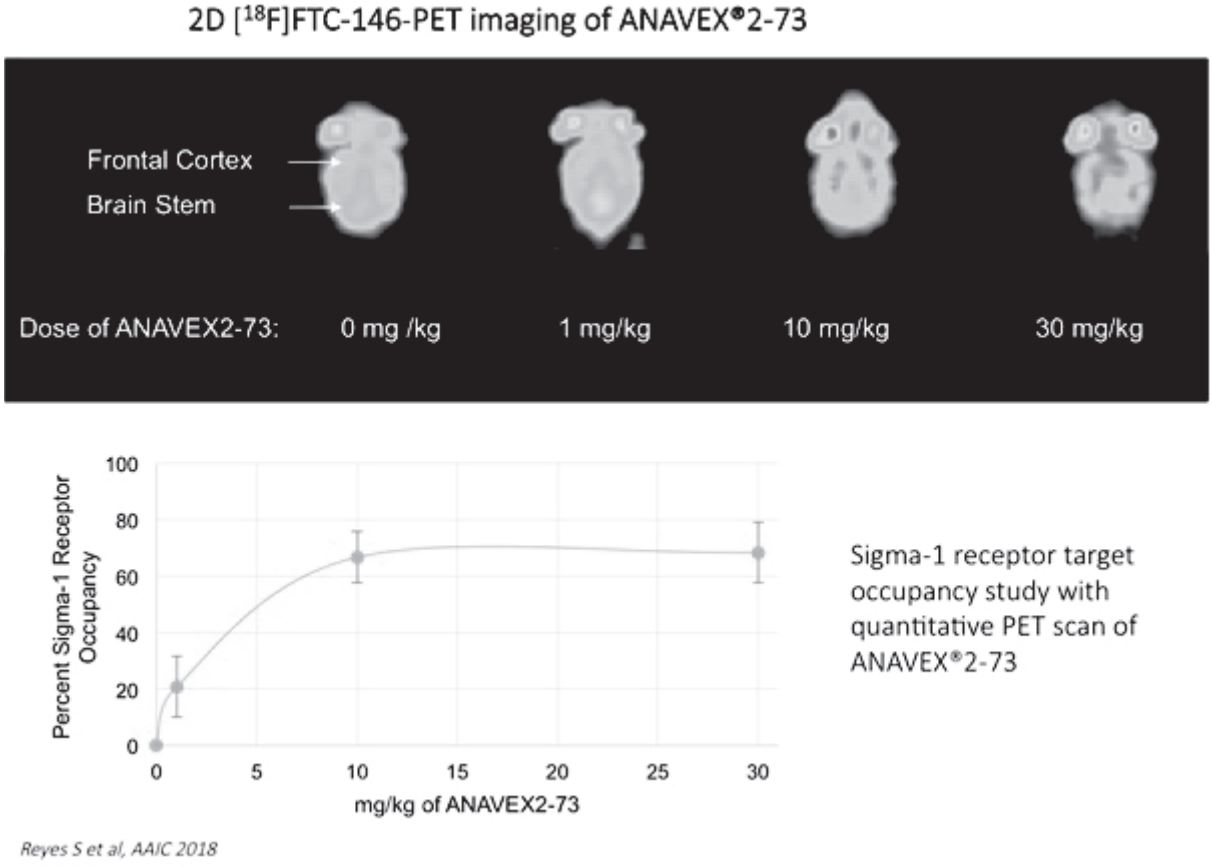
Our lead compound, ANAVEX®2-73, is being developed to treat Alzheimer's disease, Parkinson's disease and potentially other central nervous system diseases, including rare diseases, such as Rett syndrome, a rare severe neurological monogenic disorder caused by mutations in the X-linked gene, methyl-CpG-binding protein 2 ("MECP2").

We currently have two core programs and two seed programs. Our core programs are at various stages of clinical and preclinical development, in neurodegenerative and neurodevelopmental diseases.

The following table summarizes key information about our programs:



Anavex has a portfolio of compounds varying in sigma-1 receptor (S1R) binding activities. The SIGMAR1 gene encodes the S1R protein, which is an intracellular chaperone protein with important roles in cellular communication. S1R is also involved in transcriptional regulation at the nuclear envelope and restores homeostasis and stimulates recovery of cell function when activated. In order to validate the ability of our compounds to activate quantitatively the S1R, we performed, in collaboration with Stanford University, a quantitative Positron Emission Tomography (PET) imaging scan in mice, which demonstrated a dose-dependent ANAVEX®2-73 target engagement or receptor occupancy (RO) with S1R in the brain.



Reyes S et al, AAIC 2018

Cellular Homeostasis

Many diseases are possibly directly caused by chronic homeostatic imbalances or cellular stress of brain cells. In pediatric diseases like Rett syndrome or infantile spasms, the chronic cellular stress is possibly caused by the presence of a constant genetic mutation. In neurodegenerative diseases, such as Alzheimer's and Parkinson's diseases, chronic cellular stress is possibly caused by age-correlated buildup of cellular insult and hence chronic cellular stress. Specifically, defects in homeostasis of protein or ribonucleic acid ("RNA") lead to the death of neurons and dysfunction of the nervous system. The spreading of protein aggregates resulting in a proteinopathy, a characteristic finding in Alzheimer's and Parkinson's diseases that results from disorders of protein synthesis, trafficking, folding, processing or degradation in cells. The clearance of macromolecules in the brain is particularly susceptible to imbalances that result in aggregation and degeneration in nerve cells. For example, Alzheimer's disease pathology is characterized by the presence of amyloid plaques, neurofibrillary tangles, which are aggregates of hyperphosphorylated Tau protein that are a marker of other diseases known as tauopathies as well as inflammation of microglia. With the SIGMAR1 activation through SIGMAR1 agonists like ANAVEX®2-73, our approach is to restore cellular balance, i.e. homeostasis. Therapies that correct defects in cellular homeostasis might have the potential to halt or delay neurodevelopmental and neurodegenerative disease progression.

ANAVEX®2-73-specific Biomarkers

A full genomic analysis of Alzheimer's disease (AD) patients treated with ANAVEX®2-73 resulted in the identification of actionable genetic variants. A significant impact of the genomic biomarkers SIGMAR1, the direct target of ANAVEX®2-73 and COMT, a gene involved in memory function, on the drug response level was identified, leading to an early ANAVEX®2-73-specific biomarker hypothesis. It is expected that *excluding* patients with these two identified biomarker variants (approximately 10%-20% of the population) in prospective studies would identify approximately 80%-90% patients that would display clinically significant improved functional and cognitive scores. The consistency between the identified DNA and RNA data related to ANAVEX®2-73, which are considered independent of AD pathology, as well as multiple endpoints and time-points, provides support for precision medicine clinical development of ANAVEX®2-73 by using genetic biomarkers identified within the study population itself to target patients who are most likely to respond to ANAVEX®2-73 treatment in AD as well as indications like Parkinson's disease dementia (PDD) or Rett syndrome (RTT) in which ANAVEX®2-73 is currently studied.

Clinical Studies Overview

Alzheimer's Disease

In November 2016, we completed a Phase 2a clinical trial, consisting of PART A and PART B, which lasted a total of 57 weeks, for ANAVEX®2-73 in mild-to-moderate Alzheimer's patients. This open-label randomized trial met both primary and secondary endpoints and was designed to assess the safety and exploratory efficacy of ANAVEX®2-73 in 32 patients. ANAVEX®2-73 targets sigma-1 and muscarinic receptors, which have been shown in preclinical studies to reduce stress levels in the brain believed to restore cellular homeostasis and to reverse the pathological hallmarks observed in Alzheimer's disease. The Phase 2a trial demonstrated positive pharmacokinetic (PK) and pharmacodynamic (PD) data, which established a concentration-effect relationship between ANAVEX®2-73 and study measurements. These measures obtained from all patients who participated in the entire 57 weeks include exploratory cognitive and functional scores as well as biomarker signals of brain activity. Additionally, the study appears to show that ANAVEX®2-73 activity is enhanced by its active metabolite (ANAVEX19-144), which also targets the sigma-1 receptor and has a half-life approximately twice as long as the parent molecule.

Two consecutive trial extensions for the Phase 2a trial have allowed participants who completed the 52-week PART B of the study to continue taking ANAVEX®2-73, providing an opportunity to gather extended safety data for a cumulative time period of five years. In August 2020, patients completing these Phase 2a trial extensions were granted continued access to treatment with ANAVEX®2-73 through the Australian Government Department of Health – Therapeutic Goods Administration (TGA) compassionate use Special Access Scheme.

A larger Phase 2b/3 double-blind, placebo-controlled study of ANAVEX®2-73 in Alzheimer's disease commenced in August 2018. The Phase 2b/3 study will enroll approximately 450 patients for 48 weeks, randomized 1:1:1 to two different ANAVEX®2-73 doses or placebo. The trial commenced in Australia; and during fiscal 2020 additional regions were added in the United Kingdom, The Netherlands, Germany and Canada. The ANAVEX®2-73 Phase 2b/3 study design incorporates genomic precision medicine biomarkers identified in the ANAVEX®2-73 Phase 2a study. Primary and secondary endpoints will assess safety and both cognitive and functional efficacy, measured through Alzheimer's Disease Assessment Scale – Cognition (ADAS-Cog), ADCS-ADL and Clinical Dementia Rating – Sum of Boxes for cognition and function (CDR-SB).

In October 2019, we initiated a long-term open label extension study of ANAVEX®2-73, entitled the ATTENTION-AD study, for patients who have completed the 48-week Phase 2b/3 placebo-controlled trial referenced above. This study is expected to last two years and will give patients the opportunity to continue their treatment.

Rett Syndrome

In February 2016, we presented positive preclinical data for ANAVEX®2-73 in Rett syndrome, a rare neurodevelopmental disease. The study was funded by the International Rett Syndrome Foundation ("Rettsyndrome.org"). In January 2017, we were awarded a financial grant from Rettsyndrome.org of a minimum of $0.6 million to cover some of the costs of a multicenter Phase 2 clinical trial of ANAVEX®2-73 for the treatment of Rett syndrome. This award was received in quarterly instalments which commenced during fiscal 2018.

In March 2019, we commenced the first Phase 2 clinical trial in a planned Rett syndrome program of ANAVEX®2-73 for the treatment of Rett syndrome. The studies will be conducted in a range of patient age demographics and geographic regions.

The first Phase 2 study, which took place in the United States, was completed in December 2020. This trial was a randomized double-blind, placebo-controlled safety, tolerability, pharmacokinetic and efficacy study of oral liquid ANAVEX®2-73formulation in 25 adult female patients with Rett syndrome over a 7-week treatment period including ANAVEX®2-73-specific genomic precision medicine biomarkers. The primary endpoint of the trial was safety. The convenient oral liquid once-daily dosing of 5 mg ANAVEX®2-73 was well-tolerated and demonstrated dose-proportional PK (pharmacokinetics). All secondary efficacy endpoints of the trial showed statistically significant and clinically meaningful, drug exposure-dependent response in the Rett Syndrome Behaviour Questionnaire (RSBQ) Total scores, when compared to placebo, in the ITT cohort (all participants, $p = 0.048$). 66.7% of ANAVEX®2-73 treated subjects showed a statistically significant improvement in drug exposure-dependent RSBQ response as compared to 10% of the subjects on placebo in the ITT cohort (all participants, $p = 0.011$). ANAVEX®2-73 treatment resulted in a sustained improvement in Clinical Global Impression Improvement (CGI-I) scores throughout the 7-week study, when compared to placebo in the ITT cohort (all participants, $p = 0.014$). 86.7% of ANAVEX®2-73 treated subjects showed a statistically significant CGI-I response, defined as sustained improvement to treatment, as compared to 40% of the subjects on placebo in the ITT cohort (all participants, $p = 0.014$). Consistent with previous ANAVEX®2-73 clinical trials, patients carrying the common form of the SIGMAR1 gene treated with ANAVEX®2-73 experienced stronger improvements in the prespecified efficacy endpoints.

The second Phase 2 study of ANAVEX®2-73 for the treatment of Rett syndrome, called the AVATAR study, commenced in June 2019. This study is taking place in Australia and the United Kingdom using a convenient once-daily oral liquid ANAVEX®2-73 formulation at a higher dose than the U.S. based Phase 2 study for Rett syndrome. The study will evaluate the safety and efficacy of ANAVEX®2-73 in approximately 33 patients over a 7-week treatment period including ANAVEX®2-73 specific precision medicine biomarkers. All patients who participate in the study will be eligible to receive ANAVEX®2-73 under a voluntary open label extension protocol.

In July 2020, we commenced the third study of ANAVEX®2-73 for the treatment of Rett syndrome, called the EXCELLENCE study. This Phase 2/3 study in pediatric patients with Rett syndrome is using a convenient once-daily oral liquid ANAVEX®2-73 formulation. The study will evaluate the safety and efficacy of ANAVEX®2-73 in at least 69 pediatric patients, aged 5 to 18, over a 12-week treatment period incorporating ANAVEX®2-73 specific precision medicine biomarkers. All patients who participate in the study will be eligible to receive ANAVEX®2-73 under a voluntary open label extension protocol.

Parkinson's Disease

In September 2016, we presented positive preclinical data for ANAVEX®2-73 in Parkinson's disease, which demonstrated significant improvements on all measures: behavioral, histopathological, and neuroinflammatory endpoints. The study was funded by the Michael J. Fox Foundation. Additional data was announced in October 2017 from the model for experimental parkinsonism. The data presented indicates that ANAVEX®2-73 induces robust neurorestoration in experimental parkinsonism. The encouraging results we have gathered in this model, coupled with the favorable profile of this compound in the Alzheimer's disease trial, support the notion that ANAVEX®2-73 is a promising clinical candidate drug for Parkinson's disease dementia.

In October 2020, we completed a double-blind, randomized, placebo-controlled proof-of-concept Phase 2 trial with ANAVEX®2-73 in Parkinson's Disease Dementia (PDD), to study the effect of the compound on both the cognitive and motor impairment of Parkinson's disease. The Phase 2 study enrolled approximately 132 patients for 14 weeks, randomized 1:1:1 to two different ANAVEX®2-73 doses, 30mg and 50mg, or placebo. The ANAVEX®2-73 Phase 2 PDD study design incorporated genomic precision medicine biomarkers identified in the ANAVEX®2-73 Phase 2a study.

The study found that ANAVEX®2-73 was safe and well tolerated in oral doses up to 50mg once daily. The results show clinically meaningful, dose-dependent, and statistically significant improvements in the Cognitive Drug Research (CDR) computerized assessment system analysis. The study confirmed the precision medicine approach of targeting SIGMAR1 as a genetic biomarker in response to ANAVEX®2-73.

In August 2020, we announced a financial commitment by Shake It Up Australia Foundation for Parkinson's Research to fund up to 50% of the costs of an Australian clinical study to develop ANAVEX®2-73 for the disease modifying treatment of Parkinson's disease. The financial commitment would be made through private placement purchases of our common stock at 200% of the fair market value on the purchase date and will be contingent upon the completion of certain clinical trial milestones relating to the proposed clinical trial. The proposed clinical trial will use a convenient, once-daily oral ANAVEX®2-73 formulation to confirm the previously established potential disease modifying features of ANAVEX®2-73 in an animal model of Parkinson's disease. Safety and efficacy will be investigated in an appropriately powered placebo-controlled clinical study of Parkinson's disease patients over at least 48-weeks including ANAVEX®2-73-specific precision medicine biomarkers.

Frontotemporal Dementia

In July 2020, we commenced the First-in-Human Phase 1 clinical trial of ANAVEX®3-71, which was previously granted orphan drug designation for the treatment of Frontotemporal Dementia (FTD) by the FDA. ANAVEX®3-71 is an orally administered small molecule targeting sigma-1 and M1 muscarinic receptors that is designed to be beneficial for neurodegenerative diseases. In preclinical studies, ANAVEX®3-71 demonstrated disease-modifying activity against the major hallmarks of Alzheimer's disease in transgenic (3xTg-AD) mice, including cognitive deficits, amyloid and tau pathologies, as well as beneficial effects on mitochondrial dysfunction and neuroinflammation.

The Phase 1 clinical trial will be a prospective double-blind, randomized, placebo-controlled study. A total of at least 36 healthy male and female subjects will be included. Single escalating doses of ANAVEX®3-71 will be administered in order to evaluate the safety, tolerability, and pharmacokinetics (PK) of ANAVEX®3-71 and the effects of food and gender on its PK in healthy volunteers. This study is expected to be followed by longer duration dosing including patients with FTD or other dementia indications with unmet medical need, incorporating exploratory efficacy and disease biomarker measures.

Our Pipeline

Our research and development pipeline includes ANAVEX®2-73 currently in three different clinical study indications, and several other compounds in different stages of clinical and pre-clinical study.

Our proprietary SIGMACEPTOR™ Discovery Platform produced small molecule drug candidates with unique modes of action, based on our understanding of sigma receptors. Sigma receptors may be targets for therapeutics to combat many human diseases, both of neurodegenerative nature, including Alzheimer's disease, as well as of neurodevelopmental nature, like Rett syndrome. When bound by the appropriate ligands, sigma receptors influence the functioning of multiple biochemical signals that are involved in the pathogenesis (origin or development) of disease. Multiple viruses including SARS-CoV-2 (COVID-19) induce cellular stress by intrinsic mitochondrial apoptosis and other related cellular processes, in order to ensure survival and replication. Hence, it is possible that S1R could play a role in modulating the cellular response to viral infection and ameliorate pathogenesis.

Compounds that have been subjects of our research include the following:

ANAVEX®2-73 (blarcamesine)

ANAVEX®2-73 may offer a disease-modifying approach in neurodegenerative and neurodevelopmental diseases by activation of sigma-1 receptors.

In Rett syndrome, administration of ANAVEX®2-73 resulted in both significant and dose related improvements in an array of behavioral paradigms in the MECP2 HET Rett syndrome disease model. In addition, in a further experiment sponsored by Rettsyndrome.org, ANAVEX®2-73 was evaluated in automatic visual response and respiration tests in 7-month old mice, an age at which advanced pathology is evident. Vehicle-treated MECP2 mice demonstrated fewer automatic visual responses than wild-type mice. Treatment with ANAVEX®2-73 for four weeks significantly increased the automatic visual response in the MECP2 Rett syndrome disease mouse. Additionally, chronic oral dosing daily for 6.5 weeks of ANAVEX®2-73 starting at ~5.5 weeks of age was conducted in the MECP2 HET Rett syndrome disease mouse model assessed the different aspects of muscular coordination, balance, motor learning and muscular strengths, some of the core deficits observed in Rett syndrome. Administration of ANAVEX®2-73 resulted in both significant and dose related improvements in an array of these behavioral paradigms in the MECP2 HET Rett syndrome disease model.

In March 2019, we commenced the first Phase 2 clinical trial in a planned Rett syndrome program of ANAVEX®2-73 for the treatment of Rett syndrome. This study, which took place in the United States, was completed in December 2020, however two other clinical trials in Rett syndrome, the AVATAR study and the EXCELLENCE study, are still underway. The studies are being conducted in a range of patient age demographics and geographic regions, as more fully described above under *Clinical Studies Overview – Rett Syndrome*.

In May 2016 and June 2016, the FDA granted Orphan Drug Designation to ANAVEX®2-73 for the treatment of Rett syndrome and infantile spasms, respectively. In November 2019, the FDA granted to ANAVEX®2-73 the Rare Pediatric Disease (RPD) designation for the treatment of Rett syndrome. The RPD designation provides priority review by the FDA to encourage the development of treatments for rare pediatric diseases.

Further, in February 2020, the FDA granted Fast Track designation for the ANAVEX®2-73 clinical development program for the treatment of Rett syndrome. The FDA Fast Track program is designed to facilitate and expedite the development and review of new drugs to address unmet medical needs in the treatment of serious and life-threatening conditions.

For Parkinson's disease, data demonstrates significant improvements and restoration of function in a disease modifying animal model of Parkinson's disease. Significant improvements were seen on all measures tested: behavioral, histopathological, and neuroinflammatory endpoints. In October 2020, we completed a double-blind, randomized, placebo-controlled proof-of-concept Phase 2 trial with ANAVEX®2-73 in Parkinson's Disease Dementia (PDD), to study the effect of the compound on both the cognitive and motor impairment of Parkinson's disease. The Phase 2 study enrolled approximately 132 patients for 14 weeks, randomized 1:1:1 to two different ANAVEX®2-73 doses, 30mg and 50mg, or placebo. The ANAVEX®2-73 Phase 2 PDD study design incorporated genomic precision medicine biomarkers identified in the ANAVEX®2-73 Phase 2a study.

The study found that ANAVEX®2-73 was safe and well tolerated in oral doses up to 50mg once daily. The results show clinically meaningful, dose-dependent, and statistically significant improvements in the Cognitive Drug Research (CDR) computerized assessment system analysis. We anticipate conducting further clinical trials of ANAVEX®2-73 in Parkinson's disease dementia after submitting the results of the study to the FDA to obtain regulatory guidance.

In Alzheimer's disease (AD) animal models, ANAVEX®2-73 has shown pharmacological, histological and behavioral evidence as a potential neuroprotective, anti-amnesic, anti-convulsive and anti-depressive therapeutic agent, due to its potent affinity to sigma-1 receptors and moderate affinities to M1-4 type muscarinic receptors. In addition, ANAVEX®2-73 has shown a potential dual mechanism which may impact both amyloid and tau pathology. In a transgenic AD animal model Tg2576, ANAVEX®2-73 induced a statistically significant neuroprotective effect against the development of oxidative stress in the mouse brain, as well as significantly increased the expression of functional and synaptic plasticity markers that is apparently amyloid-beta independent. It also statistically alleviated the learning and memory deficits developed over time in the animals, regardless of sex, both in terms of spatial working memory and long-term spatial reference memory.

Based on the results of pre-clinical testing, we initiated and completed a Phase 1 single ascending dose (SAD) clinical trial of ANAVEX®2-73. In this Phase 1 SAD trial, the maximum tolerated single dose was defined per protocol as 55-60 mg. This dose is above the equivalent dose shown to have positive effects in mouse models of AD. There were no significant changes in laboratory or electrocardiogram (ECG) parameters. ANAVEX®2-73 was well tolerated below the 55-60 mg dose with only mild adverse events in some subjects. Observed adverse events at doses above the maximum tolerated single dose included headache and dizziness, which were moderate in severity and reversible. These side effects are often seen with drugs that target CNS conditions, including AD.

In December 2014, a Phase 2a clinical trial was initiated for ANAVEX®2-73, for the treatment of Alzheimer's disease. The open-label randomized trial was designed to assess the safety and exploratory efficacy of ANAVEX®2-73 in 32 patients with mild-to-moderate Alzheimer's disease. ANAVEX®2-73 targets sigma-1 and muscarinic receptors, which have been shown in preclinical studies to reduce stress levels in the brain believed to restore cellular homeostasis and to reverse the pathological hallmarks observed in Alzheimer's disease. The Phase 2a study met both primary and secondary objectives of the study.

In July 2018, we presented the results of a genomic DNA and RNA evaluation of the participants in the Phase 2a study. More than 33,000 genes were analyzed using unbiased, data driven, machine learning, artificial intelligence (AI) system for analyzing DNA & RNA data in patients exposed to ANAVEX®2-73. The analysis identified genetic

variants that impacted response to ANAVEX®2-73, among them variants related to the Sigma-1 receptor (SIGMAR1), the target for ANAVEX®2-73. Results showed that study participants with the common SIGMAR1 wild type gene variant, which is about 80 percent of the population worldwide, demonstrated improved cognitive (MMSE) and the functional (ADCS-ADL) scores. The results from this evaluation have been used to establish a precision medicine approach in subsequent clinical trials, since these signatures can now be applied to neurological indications tested in clinical studies with ANAVEX®2-73 including Alzheimer's disease, Parkinson's disease dementia and Rett syndrome.

ANAVEX®2-73 data presented met prerequisite information in order to progress into a Phase 2b/3 placebo-controlled study. On July 2, 2018, the Human Research Ethics Committee in Australia approved the initiation of our Phase 2b/3, double-blind, randomized, placebo-controlled 48-week safety and efficacy trial of ANAVEX®2-73 for the treatment of early Alzheimer's disease. Clinical trial sites in Canada, the United Kingdom, the Netherlands and Germany were also added. This Phase 2b/3 study design incorporates inclusion of genomic precision medicine biomarkers identified in the ANAVEX®2-73 Phase 2a study. The Phase 2b/3 study, which is expected to enroll approximately 450 patients, randomized 1:1:1 to either two different ANAVEX®2-73 doses or placebo, commenced in October 2018.

Preclinical data also validates ANAVEX®2-73 as a prospective platform drug for other neurodegenerative diseases beyond Alzheimer's disease, Parkinson's disease or Rett syndrome, more specifically, epilepsy, infantile spasms, Fragile X syndrome, Angelman syndrome, multiple sclerosis and, more recently, tuberous sclerosis complex (TSC). ANAVEX®2-73 demonstrated significant improvements in all of these indications in the respective preclinical animal models.

In a study sponsored by the Foundation for Angelman Syndrome, ANAVEX®2-73 was assessed in a mouse model for the development of audiogenic seizures. The results indicated that ANAVEX®2-73 administration significantly reduced audiogenic-induced seizures. In a study sponsored by FRAXA Research Foundation regarding Fragile X syndrome, data demonstrated that ANAVEX®2-73 restored hippocampal brain-derived neurotrophic factor (BDNF) expression to normal levels. BDNF under-expression has been observed in many neurodevelopmental and neurodegenerative pathologies. BDNF signaling promotes maturation of both excitatory and inhibitory synapses. ANAVEX®2-73 normalization of BDNF expression could be a contributing factor for the positive data observed in both neurodevelopmental and neurodegenerative disorders like Angelman and Fragile X syndromes.

Preclinical data presented also indicates that ANAVEX®2-73 demonstrates protective effects of mitochondrial enzyme complexes during pathological conditions, which, if impaired, are believed to play a role in the pathogenesis of neurodegenerative and neurodevelopmental diseases.

Preclinical data on ANAVEX®2-73 related to multiple sclerosis indicates that ANAVEX®2-73 may promote remyelination in multiple sclerosis disease. Further, data also demonstrates that ANAVEX®2-73 provides protection for oligodendrocytes ("OL's") and oligodendrocyte precursor cells ("OPC's"), as well as central nervous system neurons in addition to helping repair by increasing OPC proliferation and maturation in tissue culture.

In March 2018, we presented preclinical data of ANAVEX®2-73 in a genetic mouse model of tuberous sclerosis complex ("TSC"). TSC is a rare genetic disorder characterized by the growth of numerous benign tumors in many parts of the body with a high incidence of seizures. The new preclinical data demonstrates that treatment with ANAVEX®2-73 significantly increases survival and reduces seizures.

ANAVEX®3-71

ANAVEX®3-71 is a clinical drug candidate with a novel mechanism of action via sigma-1 receptor activation and M1 muscarinic allosteric modulation, which has been shown to enhance neuroprotection and cognition in Alzheimer's disease models. ANAVEX®3-71 is a CNS-penetrable potential disease modifying treatment for cognitive impairments. It is highly effective in very small doses against the major Alzheimer's hallmarks in transgenic (3xTg-AD) mice, including cognitive deficits, amyloid and tau pathologies, and also has beneficial effects on inflammation and mitochondrial dysfunctions. ANAVEX®3-71 indicates extensive therapeutic advantages in Alzheimer's and other protein-aggregation-related diseases given its ability to enhance neuroprotection and cognition via sigma-1 receptor activation and M1 muscarinic allosteric modulation.

A preclinical study examined the response of ANAVEX®3-71 in aged transgenic animal models and showed a significant reduction in the rate of cognitive deficit, amyloid beta pathology and inflammation with the administration of ANAVEX 3-71. In April 2016, the FDA granted Orphan Drug Designation to ANAVEX®3-71 for the treatment of Frontotemporal dementia (FTD).

During pathological conditions ANAVEX®3-71 demonstrated the formation of new synapses between neurons (synaptogenesis) without causing an abnormal increase in the number of astrocytes. In neurodegenerative diseases such as Alzheimer's and Parkinson's disease, synaptogenesis is believed to be impaired. Additional preclinical data presented also indicates that in addition to reducing oxidative stress, ANAVEX®3-71 demonstrates protective effects of mitochondrial enzyme complexes during pathological conditions, which, if impaired, are believed to play a role in the pathogenesis of neurodegenerative and neurodevelopmental diseases.

In July 2020, we commenced the first Phase 1 clinical trial of ANAVEX®3-71, with focus on the treatment of Frontotemporal Dementia (FTD) and other dementia indications with unmet medical need. The study is more fully described above under *Clinical Studies Overview – Frontotemporal Dementia*.

ANAVEX®1-41

ANAVEX®1-41 is a sigma-1 receptor agonist. Pre-clinical tests revealed significant neuroprotective benefits (i.e., protects nerve cells from degeneration or death) through the modulation of endoplasmic reticulum, mitochondrial and oxidative stress, which damages and impairs cell viability. In addition, in animal models, ANAVEX®1-41 prevented the expression of caspase-3, an enzyme that plays a key role in apoptosis (programmed cell death) and loss of cells in the hippocampus, the part of the brain that regulates learning, emotion and memory. These activities involve both muscarinic and sigma-1 receptor systems through a novel mechanism of action.

Preclinical data presented also indicates that ANAVEX®1-41 demonstrates protective effects of mitochondrial enzyme complexes during pathological conditions, which, if impaired, are believed to play a role in the pathogenesis of neurodegenerative and neurodevelopmental diseases.

ANAVEX®1066

ANAVEX®1066, a mixed sigma-1/sigma-2 ligand is designed for the potential treatment of neuropathic and visceral pain. ANAVEX®1066 was tested in two preclinical models of neuropathic and visceral pain that have been extensively validated in rats. In the chronic constriction injury model of neuropathic pain, a single oral administration of ANAVEX®1066 dose-dependently restored the nociceptive threshold in the affected paw to normal levels while leaving the contralateral healthy paw unchanged. Efficacy was rapid and remained significant for two hours. In a model of visceral pain, chronic colonic hypersensitivity was induced by injection of an inflammatory agent directly into the colon and a single oral administration of ANAVEX®1066 returned the nociceptive threshold to control levels in a dose-dependent manner. Companion studies in rats demonstrated the lack of any effects on normal gastrointestinal transit with ANAVEX®1066 and a favorable safety profile in a battery of behavioral measures.

ANAVEX®1037

ANAVEX®1037 is designed for the treatment of prostate and pancreatic cancer. It is a low molecular weight, synthetic compound exhibiting high affinity for sigma-1 receptors at nanomolar levels and moderate affinity for sigma-2 receptors and sodium channels at micromolar levels. In advanced pre-clinical studies, this compound revealed antitumor potential. It has also been shown to selectively kill human cancer cells without affecting normal/healthy cells and also to significantly suppress tumor growth in immune-deficient mice models. Scientific publications highlight the possibility that these ligands may stop tumor growth and induce selective cell death in various tumor cell lines. Sigma receptors are highly expressed in different tumor cell types. Binding by appropriate sigma-1 and/or sigma-2 ligands can induce selective apoptosis. In addition, through tumor cell membrane reorganization and interactions with ion channels, our drug candidates may play an important role in inhibiting the processes of metastasis (spreading of cancer cells from the original site to other parts of the body), angiogenesis (the formation of new blood vessels) and tumor cell proliferation.

Our compounds are in the pre-clinical and clinical testing stages of development, and there is no guarantee that the activity demonstrated in pre-clinical models will be shown in human testing.

We continue to identify and initiate discussions with potential strategic and commercial partners to most effectively advance our programs and realize maximum shareholder value. Further, we may acquire or develop new intellectual property and assign, license, or otherwise transfer our intellectual property to further our goals.

Our Target Indications

We have developed compounds with potential application to two broad categories and several specific indications. including:

Central Nervous System Diseases

- Alzheimer's disease – In 2020, an estimated 5.8 million Americans were suffering from Alzheimer's disease. The Alzheimer's Association® estimates that by 2050, this number will rise to nearly 14 million Americans. Medications on the market today treat only the symptoms of Alzheimer's disease and do not have the ability to stop its onset or its progression. There is an urgent and unmet need for both a disease modifying cure for Alzheimer's disease as well as for better symptomatic treatments.

- Parkinson's disease – Parkinson's disease is a progressive disease of the nervous system marked by tremors, muscular rigidity, and slow, imprecise movement. It is associated with degeneration of the basal ganglia of the brain and a deficiency of the neurotransmitter dopamine. Parkinson's disease afflicts more than 10 million people worldwide, typically middle-aged and elderly people. The Parkinson's disease market is expected to expand to $3.2 billion by 2021, according to business intelligence provider GBI Research.

- Rett syndrome - Rett syndrome is a rare X-linked genetic neurological and developmental disorder that affects the way the brain develops, including protein transcription, which is altered and as a result leads to severe disruptions in neuronal homeostasis. It is considered a rare, progressive neurodevelopmental disorder and is caused by a single mutation in the MECP2 gene. Because males have a different chromosome combination from females, boys who have the genetic MECP2 mutation are affected in devastating ways. Most of them die before birth or in early infancy. For females who survive infancy, Rett syndrome leads to severe impairments, affecting nearly every aspect of the child's life; severe mental retardation, their ability to speak, walk and eat, sleeping problems, seizures and even the ability to breathe easily. Rett syndrome affects approximately 1 in every 10,000-15,000 females.

- Depression - Depression is a major cause of morbidity worldwide according to the World Health Organization. Pharmaceutical treatment for depression is dominated by blockbuster brands, with the leading nine brands historically accounting for approximately 75% of total sales. However, the dominance of the leading brands is waning, largely due to the effects of patent expiration and generic competition.

- Epilepsy - Epilepsy is a common chronic neurological disorder characterized by recurrent unprovoked seizures. These seizures are transient signs and/or symptoms of abnormal, excessive or synchronous neuronal activity in the brain. According to the Centers for Disease Control and Prevention, in 2015 epilepsy affected 3.4 million Americans. Today, epilepsy is often controlled, but not cured, with medication that is categorized as older traditional anti-epileptic drugs and second generation anti-epileptic drugs. Because epilepsy afflicts sufferers in different ways, there is a need for drugs used in combination with both traditional anti-epileptic drugs and second generation anti-epileptic drugs.

- Neuropathic Pain – We define neuralgia, or neuropathic pain, as pain that is not related to activation of pain receptor cells in any part of the body. Neuralgia is more difficult to treat than some other types of pain because it does not respond well to normal pain medications. Special medications have become more specific to neuralgia and typically fall under the category of membrane stabilizing drugs or antidepressants.

Cancer

- Malignant Melanoma - Predominantly a skin cancer, malignant melanoma can also occur in melanocytes found in the bowel and the eye. Malignant melanoma accounts for 75% of all deaths associated with skin cancer. The treatment includes surgical removal of the tumor, adjuvant treatment, chemo and immunotherapy, or radiation therapy. According to IMS Health the worldwide malignant melanoma market is expected to grow to $4.4 billion by 2022.

- Prostate Cancer – Specific to men, prostate cancer is a form of cancer that develops in the prostate, a gland in the male reproductive system. The cancer cells may metastasize from the prostate to other parts of the body, particularly the bones and lymph nodes. Drug therapeutics for prostate cancer are expected to increase to nearly $13.5 billion in 2024 according to Datamonitor Healthcare.

- Pancreatic Cancer - Pancreatic cancer is a malignant neoplasm of the pancreas. In the United States, approximately 55,000 new cases of pancreatic cancer will be diagnosed this year and approximately 44,000 patients will die as a result of their cancer, according to the American Cancer Society. Sales predictions by GBI Research forecast that the market for the pharmaceutical treatment of pancreatic cancer in the United States and five largest European countries will increase to $2.9 billion by 2021.

Competition

The pharmaceutical industry is intensely competitive.

At this time, our competitors are other biomedical development companies that are trying to discover and develop compounds to be used in the treatment of Alzheimer's disease and other CNS diseases, and those companies already doing so. Those companies include Biogen (NASDAQ:BIIB), Pfizer Inc. (NYSE:PFE), Abbvie Plc (NYSE:ABBV), Novartis AG (NYSE:NVS), GlaxoSmithKline Plc (NYSE:GSK), Merck & Co. Inc. (NYSE:MRK), Eli Lilly & Co. (NYSE: LLY), Johnson & Johnson (NYSE:JNJ) and Roche Holding AG (VTX:ROG). For additional discussion of the risks related to competition, see Item 1A "Risk Factors."

Patents, Trademarks and Intellectual Property

We hold ownership or exclusive rights to nine U.S. patents, ten U.S. patent applications, and various PCT or ex-U.S. patent applications relating to our drug candidates, methods associated therewith, and to our research programs.

We own one issued U.S. patent entitled "ANAVEX®2-73 and certain anticholinesterase inhibitors composition and method for neuroprotection" claims a composition of matter of ANAVEX®2-73 directed to a novel and synergistic neuroprotective compound combined with donepezil and other cholinesterase inhibitors. This patent is expected to expire in June 2034, absent any patent term extension for regulatory delays. We own two issued U.S. patents each with claims directed to crystalline forms of ANAVEX®2-73. The first of these two patents claims crystalline forms of ANAVEX®2-73, dosage forms and compositions containing crystalline ANAVEX®2-73, and methods of treatment for Alzheimer's disease using them. This patent is expected to expire in July 2036, absent any patent term extension for regulatory delays. The second of these two patents claims pharmaceutical compositions containing a crystalline form of ANAVEX®2-73, and methods of treatment for Alzheimer's disease using the compositions. This patent is expected to expire in June 2037, absent any patent term extension for regulatory delays. We also own an issued U.S. patent that claims methods and dosage forms for treating seizures, the dosage forms containing a low-dose anti-epilepsy drug combined with either: (i) ANAVEX®2-73 and its active metabolite ANAVEX®19-144; or (ii) ANAVEX®19-144. This patent is expected to expire in October 2035, absent any patent term extension for regulatory delays. We also own an issued U.S. patent that claims methods for treating a neurodevelopmental disorder or multiple sclerosis by administering ANAVEX®2-73, ANAVEX®19-144, and/or ANAVEX®1-41, another sigma receptor ligand similar to ANAVEX®2-73. This patent is expected to expire in January 2037, absent any patent term extension for regulatory delays. In addition, we own one issued U.S. Patent with claims directed to methods of treating melanoma with a compound related to ANAVEX®2-73. This patent is expected to expire in February 2030, absent any patent term extension for regulatory delays.

We also own one issued patent with claims directed to methods for treating or preventing pain with ANAVEX®1066. This patent is expected to expire in November 2036, absent any patent term extension for regulatory delays.

For ANAVEX®2-73, ANAVEX®19-144, ANAVEX®1-41, and ANAVEX®1066, we also have granted or pending applications in Australia, Canada, China, Europe, Japan, and Hong Kong, and are expected to expire after 2035.

With regard to ANAVEX®3-71, we own exclusive rights to two issued U.S. patents with claims respectively directed to the ANAVEX®3-71 compound and methods of treating various diseases including Alzheimer's with the same. These patents are expected to expire in April 2030, and January 2030, respectively, absent any patent term extension for regulatory delays. We also own exclusive rights to related patents or applications that are granted or pending in Australia, Canada, China, Europe, Japan, Korea, New Zealand, Russia, and South Africa, and are expected to expire in January 2030.

We also own other patent applications directed to enantiomers, formulations and uses that may provide additional protection for one or more of our product candidates.

We regard patents and other intellectual property rights as corporate assets. Accordingly, we attempt to optimize the value of intellectual property in developing our business strategy including the selective development, protection, and exploitation of our intellectual property rights. In addition to filings made with intellectual property authorities, we protect our intellectual property and confidential information by means of carefully considered processes of communication and the sharing of information, and by the use of confidentiality and non-disclosure agreements and provisions for the same in contractor's agreements. While no agreement offers absolute protection, such agreements provide some form of recourse in the event of disclosure, or anticipated disclosure.

Our intellectual property position, like that of many biomedical companies, is uncertain and involves complex legal and technical questions for which important legal principles are unresolved. For more information regarding challenges to our existing or future patents, see Item 1A "Risk Factors."

Government regulation

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. A new drug must be approved by the FDA through the NDA process before it may be legally marketed in the United States. We are subject to various government regulations in connection with the development of our pipeline.

U.S. Drug Development and Regulation

In the United States, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act and its implementing regulations ("FDCA"). The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Once a drug candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An Investigational New Drug application ("IND") sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the first phase of clinical trials, the parameters to be used in monitoring the safety of the trial, and the effectiveness criteria to be evaluated should the first phase lend itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective thirty (30) days after receipt by FDA, unless FDA, within the 30-day time period, places the clinical trial on a clinical hold. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns about on-going or proposed clinical trials or non-compliance with specific FDA requirements, and the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with FDA good clinical practice ("GCP") requirements, which include a requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and/or effectiveness criteria to be evaluated. Each protocol must be submitted to FDA as part of the IND, and timely safety reports must be submitted to FDA and the investigators for serious and unexpected adverse events. An Institutional Review Board ("IRB") at each institution participating in the clinical trial must review and approve each protocol before a clinical trial may commence at the institution and must also approve the information regarding the trial as well as the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with all applicable IRB regulations.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined in certain cases:

Phase 1: The compound is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness. In most cases, initial Phase 1 clinical trials are conducted with healthy volunteers. However, where the compound being evaluated is for the treatment of severe or life-threatening diseases, such as cancer, and especially when the product may be too toxic to ethically administer to healthy volunteers, the initial human testing may be conducted on patients with the target disease or condition. Sponsors sometimes subdivide their Phase 1 clinical trials into Phase 1a and Phase 1b clinical trials. Phase 1b clinical trials are typically aimed at confirming dosage, pharmacokinetics and safety in a larger number of patients. Some Phase 1b studies evaluate biomarkers or surrogate markers that may be associated with efficacy in patients with specific types of diseases or conditions.

Phase 2: This phase involves clinical trials in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases or conditions and to confirm dosage tolerance and appropriate dosage.

Phase 3: Phase 3 clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population, generally at geographically dispersed clinical study sites. These clinical trials, often referred to as "pivotal" clinical trials, are intended to establish the overall risk-benefit ratio of the compound and provide, if appropriate, an adequate basis for product labeling.

FDA or the sponsor may suspend a clinical trial at any time on various grounds, including any finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected, serious harm to study subjects. In addition, clinical trials may be overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this committee may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

Post-approval trials may also be conducted after a drug receives initial marketing approval. These trials, often referred to as "Phase 4" trials, are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may mandate the performance of such clinical trials as a condition of approval of an NDA.

During the development of a new drug, sponsors are given several opportunities to meet with FDA. These meetings can provide an opportunity for the sponsor to share information about the progress of the application or clinical trials, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. These meetings may occur prior to the submission of an IND, at the end of Phase 2 clinical trials, or before an NDA is ultimately submitted. Sponsors typically use the meetings at the end of the Phase 2 trials to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug. Meetings at other times may be made upon request.

Concurrent with clinical trials, companies typically complete additional, animal or other non-clinical studies, develop additional information about the chemistry and physical characteristics of the drug, and finalize a process for manufacturing the product in commercial quantities in accordance with FDA's current Good Manufacturing Practices ("cGMP") requirements. The manufacturing process must consistently produce quality batches of the drug and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate the effectiveness of the packaging and that the compound does not undergo unacceptable deterioration over its shelf life.

While the IND is active, progress reports summarizing the results of ongoing clinical trials and nonclinical studies performed since the last progress report must be submitted on at least an annual basis to FDA, and written IND safety reports must be submitted to FDA and investigators for serious and unexpected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important, increased incidence of a serious adverse reaction compared to that listed in the protocol or investigator brochure.

There are also requirements governing the submission of certain clinical trials and completed trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products are required to register and disclose specified clinical trial registration and results information, which is made publicly available at www.clinicaltrials.gov. Failure to properly report clinical trial results can result in civil monetary penalties. Disclosure of clinical trial results can often be delayed until the new product or new indication being studied has been approved.

U.S. review and approval process

The results of product development, preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to FDA as part of a New Drug Application ("NDA"). The submission of an NDA is subject to the payment of substantial user fees; a waiver of which may be obtained under certain limited circumstances.

FDA reviews NDAs to determine, among other things, whether the product is safe and effective for its intended use and whether it is manufactured in a cGMP-compliant manner, which will assure and preserve the product's identity, strength, quality and purity. Under the Prescription Drug User Fee Act ("PDUFA"), FDA has a goal of ten months from the date of "filing" of a standard, completed NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because FDA has approximately two months to make a "filing" decision after the application is submitted. FDA conducts a preliminary review of all NDAs within the first sixty days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

FDA may refer an application for a new drug to an advisory committee within FDA. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether and under what conditions the application should be approved. FDA is not bound by the recommendations of such an advisory committee, but it considers advisory committee recommendations carefully when making decisions.

Before approving an NDA, FDA will also inspect the facility where the product is manufactured. FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. Before approving an NDA, FDA may also inspect one or more clinical trial sites to assure compliance with GCP requirements.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by FDA and may require additional clinical data, such as an additional pivotal Phase 3 trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, FDA may decide that the NDA does not satisfy the criteria for approval. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications.

The Pediatric Research Equity Act ("PREA"), requires IND sponsors to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

If a drug receives FDA approval, the approval may be limited to specific diseases and dosages, which could restrict the commercial value of the product. In addition, FDA may require testing and surveillance programs to monitor the safety of approved products which have been commercialized, and may require a sponsor to conduct post-marketing clinical trials, which are designed to further assess a drug's safety and effectiveness after NDA approval. FDA may also place other conditions on approval, including a requirement for a risk evaluation and mitigation strategy ("REMS") to assure the safe use of the drug. If FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescribing or dispensing of products. Marketing approval may be withdrawn for non-compliance with REMS or other regulatory requirements, or if problems occur following initial marketing.

Post-approval requirements

Once an approval is granted, FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the drug reaches the market. Later discovery of previously unknown problems with a drug may result in restrictions on the drug or even complete withdrawal of the drug from the market. After approval, some types of changes to the approved drug, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with FDA and certain state agencies and are subject to periodic unannounced inspections by FDA and certain state agencies for compliance with cGMP regulations and other laws and regulations.

Any drug product manufactured or distributed by us pursuant to FDA approval will be subject to continuing regulation by FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the drug, providing FDA with updated safety and efficacy information, drug sampling and distribution requirements, complying with certain electronic records and signature requirements, and complying with FDA promotion and advertising requirements. FDA strictly regulates labeling, advertising, promotion and other types of information regarding approved drugs that are placed on the market, and imposes requirements and restrictions on drug manufacturers, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product for a certain indication or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable governmental requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical holds on post-marketing clinical trials, enforcement letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties.

Expedited development and review programs

The FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. With regard to a fast track product, FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval.

A product is eligible for priority review if it is intended to treat a serious condition, and if approved, would provide a significant improvement in safety or efficacy compared to currently marketed products. FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. FDA endeavors to review applications with priority review designations within six months of the filing date, as compared to ten months for review of NDAs under its current PDUFA review goals.

In addition, a product may be eligible for accelerated approval. Drugs intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. Drugs receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing trials or if such trials fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

The Food and Drug Administration Safety and Innovation Act ("FDASIA") established a category of drugs referred to as "breakthrough therapies" that may be eligible to receive breakthrough therapy designation. A sponsor may seek FDA designation of a compound as a "breakthrough therapy" if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as breakthrough therapy, FDA will work to expedite the development and review of such drug.

Fast track designation, priority review and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process. However, even if a product qualifies for one or more of these programs, FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan drug designation

Under the Orphan Drug Act, FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before an NDA is submitted. After FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are publicly disclosed by FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. However, competitors, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of one of our compounds for seven years if our compound is determined to be contained within the competitor's product for the same indication or disease, or if a competitor obtains approval of the same drug as defined by the FDA. In addition, if an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity.

Marketing exclusivity

Market exclusivity provisions under the FDCA can delay the submission or approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application ("ANDA"), or an NDA submitted under Section 505(b)(2) (a "505(b)(2) NDA"), submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active ingredient for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

Foreign Sales

Sales outside the United States of potential drug compounds we develop will also be subject to foreign regulatory requirements governing human clinical trials and marketing for drugs. The requirements vary widely from country to country, but typically the registration and approval process takes several years and requires significant resources. In most cases, if the FDA has not approved a potential drug compound for sale in the United States, the potential drug compound may be exported for sale outside of the United States, only if it has been approved in any one of the following: the European Union, Canada, Australia, New Zealand, Japan, Israel, Switzerland and South Africa. There are specific FDA regulations that govern this process.

U.S. coverage and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any compound for which we may seek regulatory approval. Sales in the United States will depend in part on the availability of sufficient coverage and adequate reimbursement from third-party payors, which include government health programs such as Medicare, Medicaid, CHIP, TRICARE and the Veterans Administration, as well as managed care organizations and private health insurers. Prices at which we or our customers seek reimbursement for our therapeutic compounds can be subject to challenge, reduction or denial by payors.

The process for determining whether a payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be available. Additionally, in the United States there is no uniform policy among payors for coverage or reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. If coverage and adequate reimbursement are not available, or are available only at limited levels, successful commercialization of, and obtaining a satisfactory financial return on, any product we develop may not be possible.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for marketing, we may need to conduct expensive studies in order to demonstrate the medical necessity and cost-effectiveness of any products, which would be in addition to the costs expended to obtain regulatory approvals. Third-party payors may not consider our compounds to be medically necessary or cost-effective compared to other available therapies, or the rebate percentages required to secure favorable coverage may not yield an adequate margin over cost or may not enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development.

Fraud and Abuse Laws

Federal and state health care laws and regulations restrict business practices in the biopharmaceutical industry. In the biopharmaceutical industry, there are a number of federal and state health care regulatory requirements that apply to entities, including, but not limited to, the federal and state fraud and abuse laws. These laws include, but are not limited to, anti-kickback and self-referral law, civil false claims act law, criminal false statement law, civil monetary penalty laws, exclusion law, and other civil, criminal, and administrative laws. Health care laws, regulations, and guidance continuously evolve and are thereby subject to constant change.

The Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), among other things, prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration, whether directly or indirectly and overtly or covertly in cash or in kind, in return for, or to induce the referral of an individual for the:

- furnishing or arranging for the furnishing of items or services reimbursable in whole or in part under Medicare, Medicaid or other federal healthcare programs; or
- purchase, lease, or order of, or the arrangement or recommendation of the purchasing, leasing, or ordering of any item or service reimbursable in whole or in part under Medicare, Medicaid or other federal healthcare programs.

There are a number of narrow safe harbors to the Federal Anti-Kickback Statute. Such safe harbors permit certain payments and business practices that, although they would otherwise potentially implicate the Federal Anti-Kickback Statute, are not treated as an offense under the same if all of the requirements of the specific applicable safe harbor are met. Actual knowledge of the statute or specific intent to violate it is not required in order for a person or entity to have committed a violation.

The Federal Anti-Kickback Statute applies to certain arrangements with healthcare providers, product end users and other parties, including marketing arrangements and discounts and other financial incentives offered in connection with the sales of our products. Regulatory authorities may determine that certain marketing, pricing, or other activities violate the Federal Anti-Kickback Statute or other applicable laws. Noncompliance with the Federal Anti-Kickback Statute can result in civil, administrative and/or criminal penalties, restrictions on the ability to operate in certain jurisdictions, and exclusion from participation in Medicare, Medicaid or other federal healthcare programs. In addition, non-compliance can result in the need to curtail and/or restructure operations. Any penalties, damages, fines, exclusions, curtailment or restructuring of operations could adversely affect the ability to operate a business, financial condition, and results of operations. A violation of the Federal Anti-Kickback Statute can serve as a false or fraudulent claim for purposes of the civil False Claims Act and the civil monetary penalties statute.

The Ethics in Patient Referrals Act, commonly known as the "Stark Law," 42 U.S.C. § 1395nn, prohibits a physician from making referrals for certain "designated health services" payable by Medicare to an entity in which the physician or an immediate family member of such physician has an ownership or investment interest or with which the physician has entered into a compensation arrangement, unless a statutory exception applies. There are a number of exceptions to the Stark Law. Such exceptions permit certain payments and arrangements that, although they would otherwise potentially implicate the Stark Law, are not treated as a violation under the same if the requirements of the specific exceptions are met. Violation of the Stark Law could result in denial of payment, disgorgement of reimbursements received under a noncompliance arrangement, civil penalties, damages and exclusion from Medicare or other governmental programs. These requirements are highly technical and there can be no guarantee that regulatory authorities will not determine or assert that arrangements are in violation of the Stark Law and do not otherwise meet applicable Stark Law exceptions.

The federal false statements statute, 42 U.S.C. § 1320a-7b(a), prohibits knowingly and willfully falsifying, concealing, or omitting a material fact or making any materially false statement in connection with the delivery of health care benefits, items, or services. Similarly, 18 U.S.C. § 1035 prohibits a person or entity, in any matter involving a health care benefit program, from knowingly or willfully falsifying, concealing, or covering up by any trick, scheme, or device a material fact; making any materially false, fictitious, or fraudulent statements or representations; or making or using any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry. In addition to criminal penalties, violation of these statutes may result in collateral administrative sanctions, including exclusion from participation in Medicare, Medicaid and other federal health care programs.

18 U.S.C. § 669 prohibits knowingly and willfully embezzling, stealing, or otherwise without authority converting to the use of any person or entity other than the rightful owner, or intentionally misapplying any of the moneys, funds, securities, premiums, credits, property, or other assets of a health care benefit program. In addition to criminal penalties, violation of this statute may result in collateral administrative sanctions, including exclusion from participation in Medicare, Medicaid and other federal health care programs.

The criminal health care fraud statute, 18 U.S.C. § 1347, establishes criminal liability for whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice to defraud any health care benefit program, or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, in connection with the delivery of or payment for health care benefits, items, or services. In addition to criminal penalties, violation of this statute may result in collateral administrative sanctions, including exclusion from participation in Medicare, Medicaid and other federal health care programs. A person or entity need not have actual knowledge of this law or specific intent to commit a violation of this law.

18 U.S.C. § 1518 establishes criminal liability for whoever willfully prevents, obstructs, misleads, delays or attempts to prevent, obstruct, mislead, or delay the communication of information or records relating to a violation of a Federal health care offense to a criminal investigator. In addition to criminal penalties, violation of this statute may result in collateral administrative sanctions, including exclusion from participation in Medicare, Medicaid and other federal health care programs.

18 U.S.C. § 286 establishes criminal liability for whoever enters into any agreement, combination, or conspiracy to defraud the United States, or any department or agency thereof, by obtaining or aiding to obtain the payment or allowance of any false, fictitious or fraudulent claim. In addition to criminal penalties, violation of this statute may result in collateral administrative sanctions, including exclusion from participation in Medicare, Medicaid and other federal health care programs.

18 U.S.C. § 287 establishes criminal liability for whoever knowingly makes or presents a false, fictitious or fraudulent claim to the United States Government, including any department or agency thereof. In addition to criminal penalties, violation of this statute may result in collateral administrative sanctions, including exclusion from participation in Medicare, Medicaid and other federal health care programs.

The Federal False Claims Act, 31 U.S.C. § 3729, et seq., provides, in part, that the federal government—or a private party on behalf of the government—may bring a lawsuit against any person whom it believes has knowingly presented, or caused to be presented, a false or fraudulent claim for payment, or who has made a false statement or used a false record to get a claim paid or to avoid, decrease or conceal an obligation to pay money to the federal government or who has knowingly retained an overpayment. Knowledge under the Federal False Claims Act means actual knowledge, deliberate indifference, or reckless disregard. In addition, amendments in 1986 to the Federal False Claims Act have made it easier for private parties to bring whistleblower lawsuits against companies.

The civil monetary penalties law, 42 U.S.C. § 1320a-7a, provides, in part, that the federal government may seek civil monetary penalties against any person who presents or causes to be presented claims to a Federal health care program that the person knows or should know is for an item or services that was not provided as claimed or is false or fraudulent, or the person has made a false statement or used a false record to get a claim paid. The federal government may also seek civil monetary penalties for a wide variety of other conduct, including offering remuneration to influence a Medicare or Medicaid beneficiary's selection of providers and violations of the Federal Anti-Kickback Statute.

Violations of the Federal False Claims Act and/or the Civil Monetary Penalties Law can result in penalties ranging from $11,665 to $23,331 for each false claim violation of the Federal False Claims Act and varying amounts based

on the type of violation of the Civil Monetary Penalties Law, plus up to three times the amount of damages that the federal government sustained. In addition, the federal government may also seek exclusion from participation in all federal health care programs.

42 U.S.C. Section 1320a-7 provides that individuals and entities can be mandatorily or permissively excluded from participation in federal health care programs. The grounds for mandatory exclusion include, but are not limited to, conviction for a criminal offense related to the delivery of an item or service reimbursed under a federal or state health care program, and a conviction related to health care fraud. The grounds for permissive exclusion include, but are not limited to, criminal offenses relating to fraud inside and outside of health care, convictions related to obstruction of an investigation or audit, and/or failure to disclose certain required information. Exclusion from federal health care programs—whether mandatory or permissive—may mean that we would not be entitled to participation in federal and/or state health care programs for services rendered.

State Fraud and Abuse Provisions

Many states have also adopted some form of anti-kickback and anti-referral laws and false claims acts and civil monetary penalties and other fraud and abuse provisions that apply regardless of payer, in addition to items and services reimbursed under Medicaid and other state programs. A determination of liability under such laws could result in fines, penalties, and exclusion, as well as restrictions on the ability to operate in these jurisdictions.

Corporate liability can be present as a result of the illegal activities of employees, representatives, contractors, collaborators, agents, subsidiaries, or affiliates, even if they were not explicitly authorized. There can be no assurance that all employees, representatives, contractors, collaborators, agents, subsidiaries or affiliates will comply with the foregoing laws at all times. Violation of the aforementioned and other laws could result in whistleblower complaints, investigations, sanctions, settlements, prosecution, government oversight and reporting, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions or other administrative remedies, suspension and/or debarment from contracting with certain governments or other persons, the loss of privileges, reputational harm, contract damages, adverse media coverage and other collateral consequences. In addition, corporate directors, officers, employees, and other representatives who engage in violations of these and other laws may face imprisonment, fines, and penalties. If any subpoenas or investigations are launched, or governmental or other sanctions are imposed, or if a company does not prevail in any possible civil or criminal litigation, business, financial condition, and results of operations could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees. Enforcement actions and sanctions could further harm business, financial condition, and results of operations. Any of the consequences contained in this paragraph and section could adversely affect the ability to operate the business, financial condition, and the results of operations.

Health Insurance Portability and Accountability Act

The Health Insurance Portability and Accountability Act, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and implementing regulations thereunder (collectively, "HIPAA") requires certain healthcare providers, health plans and healthcare clearinghouses who conduct specified electronic healthcare transactions ("covered entities"), as well as their independent contractors and agents who conduct certain activities involving protected health information on their behalf ("business associates") to comply with enumerated requirements relating to the privacy, security and transmission of protected health information. Failure to comply with HIPAA can result in corrective action, as well as civil fines and penalties and government oversight. Among other changes, HITECH made HIPAA security standards directly applicable to business associates, increased the tiered civil and criminal fines and penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file actions to enforce HIPAA. Further, the breach notification rule implemented under HITECH requires covered entities to notify affected individuals, the U.S. Department of Health and Human Services Office of Civil Rights ("OCR"), the agency that enforces HIPAA, and for breaches affecting more than 500 individuals, the media, of any breaches of unsecured protected health information. HIPAA does not create a private right of action for individuals, though individuals may submit complaints related to HIPAA to OCR.

Patient Protection and Affordable Care Act

In the United States, there have been, and continue to be multiple legislative and regulatory changes and proposed changes regarding the healthcare system that could impact our business. Policymakers and third party reimbursement programs (i.e. payors) have articulated the goals of controlling healthcare costs, improving quality and/or expanding access in connection with these healthcare reform efforts. As a leading example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA"), was passed, ushering in significant changes to the way healthcare is financed in the United States. With respect to impacts specific to the U.S. pharmaceutical industry, among other things, the ACA:

- increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program and extended the rebate program to include Medicaid managed care organizations as well as Medicaid fee-for-service programs;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, correspondingly increasing manufacturers' Medicaid rebate liability;
- created a new methodology by which average manufacturing price is calculated for drugs that are inhaled, infused, instilled, implanted or injected and not generally dispensed through retail community pharmacies;
- established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic products;
- expanded the availability of lower drug pricing under the 340B drug pricing program to additional types of covered entities;
- created a new partial prescription drug benefit for Medicare recipients under the Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- amended the Public Health Service Act to create an abbreviated approval pathway for biological products that are demonstrated to be biosimilar to or interchangeable with an FDA-approved biological product;
- added a requirement to annually report product samples that manufacturers and distributors provide to physicians;
- established new requirements, known as "Sunshine Act" requirements for manufacturers of products reimbursed by Medicare, Medicaid or the Children's Health Insurance Program ("CHIP") to collect and annually report detailed data to the Centers for Medicare and Medicaid Services ("CMS") regarding payments or other transfers of value to physicians and teaching hospitals ("covered recipients"), as well as any ownership or investment interest held by physicians and their immediate family members. The reporting data must be accompanied by an attestation as to the accuracy of the data and failure to timely and accurately submit required information may result in civil monetary penalties;
- established a Center for Medicare & Medicaid Innovation at CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drugs;
- created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- expanded healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, and enhanced penalties for noncompliance, which are applicable beyond the U.S. pharmaceutical industry (e.g. to other types of healthcare entities) but also are of specific relevance to the U.S. pharmaceutical industry.

The Bipartisan Budget Act of 2018 amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Further, the Substance-Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act ("SUPPORT Act") amended the

Sunshine Act to expand the definition of covered recipient for whom applicable manufacturers must collect ad report data to include physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse mid-wives for data reported on or after January 1, 2022.

There have been multiple judicial challenges to certain aspects of the ACA, as well as Congressional efforts to repeal or replace the ACA, and efforts by the Trump administration to delay or circumvent the implementation of certain ACA requirements. For example, the Tax Cuts and Jobs Act of 2017 repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain minimum essential health care insurance, commonly known as the "individual mandate." On December 14, 2018, a U.S. District Court in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit affirmed the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court has agreed to review the case and oral arguments heard oral arguments in November 2020. Therefore, ongoing force and effect of certain or all of the provisions of the ACA remain in a state of uncertainty at this current time.

Research and Development Expenses

Historically, a significant portion of our operating expenses has related to research and development. See our Consolidated Financial Statements contained elsewhere in this Annual Report for costs and expenses related to research and development, and other financial information for fiscal years 2020 and 2019.

Scientific Advisors

We are advised by scientists and physicians with experience relevant to our Company and our product candidates. Our scientific advisors include clinicians and scientists who are affiliated with a number of highly regarded medical institutions.

Employees

We currently have twenty full-time employees, and we retain several independent contractors on a regular or as-needed basis. We believe that we have good relations with our employees.

Available Information

Our internet website address is www.anavex.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to section 13(a) or 15(d) of the Exchange Act are available free of charge through our website. We include our website address in this report only as an inactive textual reference and do not intend it to be an active link to our website. The contents of our website are not incorporated into this report.

ITEM 1A. RISK FACTORS

In addition to other information in this Annual Report on Form 10-K, the following risk factors should be carefully considered in evaluating our business because such factors may have a significant impact on our business, operating results, liquidity and financial condition. As a result of the risk factors set forth below, actual results could differ materially from those projected in any forward-looking statements. Additional risks and uncertainties not presently known to us, or that we currently consider to be immaterial, may also impact our business, operating results, liquidity and financial condition. If any such risks occur, our business, operating results, liquidity and financial condition could be materially affected in an adverse manner. Under such circumstances, the trading price of our securities could decline, and you may lose all or part of your investment.

Risks Related to our Company

We have had a history of losses and no revenue, which raises a risk regarding our ability to continue as a going concern in the future.

Since inception through September 30, 2020, we have accumulated a deficit of approximately $160 million. We can offer no assurance that we will ever operate profitably or that we will generate positive cash flow in the future. To date, we have not generated any revenues from our operations. Our history of losses and no revenues creates a greater risk of our continued ability to continue as a going concern in the future. As a result, our management expects the business to continue to experience negative cash flows for the foreseeable future and cannot predict when, if ever, our business might become profitable. We will need to raise additional funds, and such funds may not be available on commercially acceptable terms, if at all. If we are unable to raise funds on acceptable terms, we may not be able to execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements. This may seriously harm our business, financial condition and results of operations.

We are an early stage pharmaceutical research and development company and may never be able to successfully develop marketable products or generate any revenue. We have a very limited relevant operating history upon which an evaluation of our performance and prospects can be made. There is no assurance that our future operations will result in profits. If we cannot generate sufficient revenues, we may suspend or cease operations.

We are an early stage company and have not generated any revenues to date and have no operating history. All of our potential drug compounds are in the concept stage or early clinical development stage. Moreover, we cannot be certain that our research and development efforts will be successful or, if successful, that our potential drug compounds will ever be approved for sales to pharmaceutical companies or generate commercial revenues. We have no relevant operating history upon which an evaluation of our performance and prospects can be made. We are subject to all of the business risks associated with a new enterprise, including, but not limited to, risks of unforeseen capital requirements, failure of potential drug compounds either in non-clinical testing or in clinical trials, failure to establish business relationships and competitive disadvantages against larger and more established companies. If we fail to become profitable, we may suspend or cease operations.

We will need additional funding and may be unable to raise additional capital when needed, which would force us to delay, reduce or eliminate our research and development activities.

We will need to raise additional funding and the current economic conditions may have a negative impact on our ability to raise additional needed capital on terms that are favorable to our Company or at all. We may not be able to generate significant revenues for several years, if at all. Until we can generate significant revenues, if ever, we expect to satisfy our future cash needs through equity or debt financing. We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research and development activities.

Risks Related to our Business

Even if we are able to develop our potential drug compounds, we may not be able to receive regulatory approval, or if approved, we may not be able to generate significant revenues or successfully commercialize our products, which will adversely affect our financial results and financial condition and we will have to delay or terminate some or all of our research and development plans which may force us to cease operations.

All of our potential drug compounds will require extensive additional research and development, including non-clinical testing and clinical trials, as well as regulatory approvals, before we can market them. In particular, human therapeutic products are subject to rigorous non-clinical and clinical testing and other approval procedures of the FDA and similar regulatory authorities in other countries. Various federal statutes and regulations also govern or influence testing, manufacturing, safety, labeling, storage, and record-keeping related to such products and their marketing. We cannot predict if or when any of the potential drug compounds we intend to develop will be approved for marketing. There are many reasons that we may fail in our efforts to develop our potential drug compounds. These include:

- the possibility that non-clinical testing or clinical trials may show that our potential drug compounds are ineffective and/or cause harmful side effects;
- regulators may not authorize us to commence or continue a clinical trial or may impose a clinical hold or may limit the conduct of a clinical trial through the imposition of a partial clinical hold;
- the number of patients required for clinical trials for our drug candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or the duration of these clinical trials may be longer than we anticipate;
- our third-party contractors, including investigators, may fail to meet their contractual obligations to us in a timely manner, or at all, or may fail to comply with regulatory requirements;
- our potential drug compounds may prove to be too expensive to manufacture or administer to patients;
- our potential drug compounds may fail to receive necessary regulatory approvals from the United States Food and Drug Administration or foreign regulatory authorities in a timely manner, or at all;
- even if our potential drug compounds are approved, we may not be able to produce them in commercial quantities or at reasonable costs;
- even if our potential drug compounds are approved, they may not achieve commercial acceptance;
- regulatory or governmental authorities may apply restrictions to any of our potential drug compounds, which could adversely affect their commercial success; and
- the proprietary rights of other parties may prevent us or our potential collaborative partners from marketing our potential drug compounds.

If we fail to develop our potential drug compounds, our financial results and financial condition will be adversely affected, we will have to delay or terminate some or all of our research and development plans and may be forced to cease operations.

Our research and development plans will require substantial additional future funding which could impact our operations and financial condition. Without the required additional funds, we will likely cease operations.

It will take several years before we can develop potentially marketable products, if at all. Our research and development plans will require substantial additional capital, arising from costs to:

- conduct research, non-clinical testing and human studies;
- establish pilot scale and commercial scale manufacturing processes and facilities; and
- establish and develop quality control, regulatory, marketing, sales, finance and administrative capabilities to support these programs.

Our future operating and capital needs will depend on many factors, including:

- the pace of scientific progress in our research and development programs and the magnitude of these programs;
- the scope and results of pre-clinical testing and human studies;
- the time and costs involved in obtaining regulatory approvals;
- the time and costs involved in preparing, filing, prosecuting, securing, maintaining and enforcing patents;
- competing technological and market developments;
- our ability to establish additional collaborations;
- changes in our existing collaborations;
- the cost of manufacturing scale-up; and
- the effectiveness of our commercialization activities.

We base our outlook regarding the need for funds on many uncertain variables. Such uncertainties include the success of our research initiatives, regulatory approvals, the timing of events outside our direct control such as negotiations with potential strategic partners and other factors. Any of these uncertain events can significantly change our cash requirements as they determine such one-time events as the receipt or payment of major milestones and other payments.

Additional funds will be required to support our operations and if we are unable to obtain them on favorable terms, we may be required to cease or reduce further research and development of our drug product programs, sell some or all our intellectual property, merge with another entity or cease operations.

We have received fast track designation for one of our compounds and may seek such designation or breakthrough therapy and priority review for other compounds in the future. Fast track designation or breakthrough therapy designation may not actually lead to a faster FDA review and approval process.

For some of our compounds, including ANAVEX®2-73, we hope to benefit from FDA's fast track and priority review programs. In February 2020, the FDA granted Fast Track designation for the ANAVEX®2-73 clinical development program for the treatment of Rett syndrome. However, the fast-track designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Under FDA policies, a compound is eligible for priority review, or review within a six-month time frame from the time a complete NDA is accepted for filing, if the compound provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. A fast-track designated compound would ordinarily meet the FDA's criteria for priority review.

Fast track or breakthrough therapy designation for our compounds may not actually lead to a faster review process, and a delay in the review process or in the approval of our compounds will delay revenue from their potential sales and will increase the capital necessary to fund these compound development programs.

We have received orphan drug designation for several of our compounds, but we may be unable to maintain any benefits associated with orphan drug designation, including market exclusivity.

Under the Orphan Drug Act, FDA may grant orphan designation to a drug intended to treat a rare disease or condition or for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for a disease or condition will be recovered from sales in the United States for that drug. If a product that has orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity.

We have received orphan drug designation for several of our compounds, but exclusive marketing rights in the United States may be limited if we seek FDA marketing approval for an indication broader than the orphan designated

indication. Additionally, any compound with orphan drug designation may lose such designation if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, others may obtain orphan drug exclusivity for products addressing the same diseases or conditions as products we are developing, thus limiting our ability to compete in the markets addressing such diseases or conditions for a significant period of time.

If we fail to demonstrate efficacy in our non-clinical studies and clinical trials our future business prospects, financial condition and operating results will be materially adversely affected.

The success of our research and development efforts will be greatly dependent upon our ability to demonstrate potential drug compound efficacy in non-clinical studies, as well as in clinical trials. Non-clinical studies involve testing potential drug compounds in appropriate non-human disease models to demonstrate efficacy and safety. Regulatory agencies evaluate these data carefully before they will approve clinical testing in humans. If certain non-clinical data reveals potential safety issues or the results are inconsistent with an expectation of the potential drug compound's efficacy in humans, the regulatory agencies may require additional more rigorous testing before allowing human clinical trials. This additional testing will increase program expenses and extend timelines. We may decide to suspend further testing on our potential drug compounds if, in the judgment of our management and advisors, the non-clinical test results do not support further development.

Moreover, success in non-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and non-clinical testing. The clinical trial process may fail to demonstrate that our potential drug compounds are safe for humans and effective for indicated uses. This failure would cause us to abandon a drug candidate and may delay development of other potential drug compounds. Any delay in, or termination of, our non-clinical testing or clinical trials will delay the filing of an IND and NDA with the Food and Drug Administration or the equivalent applications with pharmaceutical regulatory authorities outside the United States and, ultimately, our ability to commercialize our potential drug compounds and generate product revenues. In addition, we expect that our early clinical trials will involve small patient populations. Because of the small sample size, the results of these early clinical trials may not be indicative of future results. Also, the IND process may be extremely costly and may substantially delay the development of our potential drug compounds. Moreover, positive results of non-clinical tests will not necessarily indicate positive results in subsequent clinical trials.

Following successful non-clinical testing, potential drug compounds will need to be tested in a clinical development program to provide data on safety and efficacy prior to becoming eligible for product approval and licensure by regulatory agencies. From the first human trial through to regulatory approval can take many years and 10-12 years is not unusual for certain compounds.

If any of our future clinical development potential drug compounds become the subject of problems, our ability to sustain our development programs will become critically compromised. For example, efficacy or safety concerns may arise, whether or not justified, that could lead to the suspension or termination of our clinical programs. Examples of problems that could arise include, among others:

- efficacy or safety concerns with the potential drug compounds, even if not justified;
- manufacturing difficulties or concerns;
- regulatory proceedings subjecting the potential drug compounds to potential recall;
- publicity affecting doctor prescription or patient use of the potential drug compounds;
- pressure from competitive products; or
- introduction of more effective treatments.

Each clinical phase is designed to test attributes of the drug and problems that might result in the termination of the entire clinical plan can be revealed at any time throughout the overall clinical program. The failure to demonstrate efficacy in our clinical trials would have a material adverse effect on our future business prospects, financial condition and operating results.

If we do not obtain the support of qualified scientific collaborators, our revenue, growth and profitability will likely be limited, which would have a material adverse effect on our business.

We will need to establish relationships with leading scientists and research institutions. We believe that such relationships are pivotal to establishing products using our technologies as a standard of care for various indications. Additionally, although in discussion, there is no assurance that our current research partners will continue to work with us or that we will be able to attract additional research partners. If we are not able to establish scientific relationships to assist in our research and development, we may not be able to successfully develop our potential drug compounds. If this happens, our business will be adversely affected.

We may not be able to develop, market or generate sales of our products to the extent anticipated. Our business may fail and investors could lose all their investment in our Company.

Assuming that we are successful in developing our potential drug compounds and receiving regulatory clearances to market our products, our ability to successfully penetrate the market and generate sales of those products may be limited by a number of factors, including the following:

- If our competitors receive regulatory approvals for and begin marketing similar products in the United States, the European Union, Japan and other territories before we do, greater awareness of their products as compared to ours will cause our competitive position to suffer;
- Information from our competitors or the academic community indicating that current products or new products are more effective or offer compelling other benefits than our future products could impede our market penetration or decrease our future market share; and
- The pricing and reimbursement environment for our future products, as well as pricing and reimbursement decisions by our competitors and by payers, may have an effect on our revenues.

If this happens, our business will be adversely affected.

None of our potential drug compounds may reach the commercial market for a number of reasons and our business may fail.

Successful research and development of pharmaceutical products is high risk. Most products and development candidates fail to reach the market. Our success depends on the discovery of new drug compounds that we can commercialize. It is possible that our products may never reach the market for a number of reasons. They may be found ineffective or may cause harmful side-effects during non-clinical testing or clinical trials or fail to receive necessary regulatory approvals. We may find that certain products cannot be manufactured at a commercial scale and, therefore, they may not be economical to produce. Our potential products could also fail to achieve market acceptance or be precluded from commercialization by proprietary rights of third parties. Our patents, patent applications, trademarks and other intellectual property may be challenged, and this may delay or prohibit us from effectively commercializing our products. Furthermore, we do not expect our potential drug compounds to be commercially available for a number of years, if at all. If none of our potential drug compounds reach the commercial market, our business will likely fail and investors will lose all of their investment in our Company. If this happens, our business will be adversely affected.

If our competitors succeed in developing products and technologies faster or that are more effective or with a better profile than our own, or if scientific developments change our understanding of the potential scope and utility of our potential products, then our technologies and future products may be rendered undesirable or obsolete.

We face significant competition from industry participants that are pursuing technologies in similar disease states to those that we are pursuing and are developing pharmaceutical products that are competitive with our products. Nearly all of our industry competitors have greater capital resources, larger overall research and development staffs and facilities, and a longer history in drug discovery and development, obtaining regulatory approval and pharmaceutical product manufacturing and marketing than we do. With these additional resources, our competitors may be able to respond to the rapid and significant technological changes in the biotechnology and pharmaceutical industries faster than we can. Our future success will depend in large part on our ability to maintain a competitive position with respect to these technologies. Rapid technological development, as well as new scientific developments, may result in our products becoming obsolete before we can recover any of the expenses incurred to develop them. For example,

changes in our understanding of the appropriate population of patients who should be treated with a targeted therapy like we are developing may limit the drug's market potential if it is subsequently demonstrated that only certain subsets of patients should be treated with the targeted therapy.

Our reliance on third parties, such as university laboratories, contract manufacturing organizations and contract or clinical research organizations, may result in delays in completing, or a failure to complete, non-clinical testing or clinical trials if they fail to perform under our agreements with them.

In the course of product development, we may engage university laboratories, other biotechnology companies or contract or clinical manufacturing organizations to manufacture drug material for us to be used in non-clinical and clinical testing and contract research organizations to conduct and manage non-clinical and clinical studies. If we engage these organizations to help us with our non-clinical and clinical programs, many important aspects of this process have been and will be out of our direct control. If any of these organizations we may engage in the future fail to perform their obligations under our agreements with them or fail to perform non-clinical testing and/or clinical trials in a satisfactory manner, we may face delays in completing our clinical trials, as well as commercialization of any of our potential drug compounds. Furthermore, any loss or delay in obtaining contracts with such entities may also delay the completion of our clinical trials, regulatory filings and the potential market approval of our potential drug compounds.

If we fail to compete successfully with respect to partnering, licensing, mergers, acquisitions, joint venture and other collaboration opportunities, we may be limited in our ability to research and develop our potential drug compounds.

Our competitors compete with us to attract established biotechnology and pharmaceutical companies or organizations for partnering, licensing, mergers, acquisitions, joint ventures or other collaborations. Collaborations include contracting with academic research institutions for the performance of specific scientific testing. If our competitors successfully enter into partnering arrangements or license agreements with academic research institutions, we will then be precluded from pursuing those specific opportunities. Since each of these opportunities is unique, we may not be able to find a substitute. Other companies have already begun many drug development programs, which may target diseases that we are also targeting, and have already entered into partnering and licensing arrangements with academic research institutions, reducing the pool of available opportunities.

Universities and public and private research institutions also compete with us. While these organizations primarily have educational or basic research objectives, they may develop proprietary technology and acquire patent applications and patents that we may need for the development of our potential drug compounds. In some instances, we will attempt to license this proprietary technology, if available. These licenses may not be available to us on acceptable terms, if at all. If we are unable to compete successfully with respect to acquisitions, joint venture and other collaboration opportunities, we may be limited in our ability to develop new products.

The use of any of our products in clinical trials may expose us to liability claims, which may cost us significant amounts of money to defend against or pay out, causing our business to suffer.

The nature of our business exposes us to potential liability risks inherent in the testing, manufacturing and marketing of our products. We currently have one drug compound in clinical trials, however, when any of our products enter clinical trials or become marketed products, they could potentially harm people or allegedly harm people possibly subjecting us to costly and damaging product liability claims. Some of the patients who participate in clinical trials are already ill when they enter a trial or may intentionally or unintentionally fail to meet the exclusion criteria. The waivers we obtain may not be enforceable and may not protect us from liability or the costs of product liability litigation. Although we intend to obtain product liability insurance, which we believe is adequate, we are subject to the risk that our insurance will not be sufficient to cover claims. The insurance costs along with the defense or payment of liabilities above the amount of coverage could cost us significant amounts of money and management distraction from other elements of the business, causing our business to suffer.

If we are unable to safeguard against security breaches with respect to our information systems, our business may be adversely affected.

In the course of our business, we gather, transmit and retain confidential information through our information systems. Although we endeavor to protect confidential information through the implementation of security technologies, processes and procedures, it is possible that an individual or group could defeat security measures and access sensitive

information about our business and employees. Any misappropriation, loss or other unauthorized disclosure of confidential information gathered, stored or used by us could have a material impact on the operation of our business, including damaging our reputation with our employees, third parties and investors. We could also incur significant costs implementing additional security measures and organizational changes, implementing additional protection technologies, training employees or engaging consultants. In addition, we could incur increased litigation as a result of any potential cyber-security breach. We are not aware that we have experienced any material misappropriation, loss or other unauthorized disclosure of confidential or personally identifiable information as a result of a cyber-security breach or other act, however, a cyber-security breach or other act and/or disruption to our information technology systems could have a material adverse effect on our business, prospects, financial condition or results of operations.

Even if we receive regulatory approval for one or more compounds, we will be subject to continuing regulatory obligations and ongoing regulatory review, which may result in significant additional expense. Additionally, our compounds, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties, if we fail to comply with regulatory requirements or if we experience unanticipated problems with our compounds, when and if any of them are approved.

Following potential approval of any our compounds, FDA may impose significant restrictions on a drug's indicated uses or marketing or require potentially costly and time-consuming post-approval studies, post-market surveillance or clinical trials to monitor the safety and efficacy of the drug. FDA may also require a Risk Evaluation and Mitigation Strategy ("REMS") as a condition of approval of one or more of our compounds, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use of the drug. Additional REMS elements may include restricted distribution methods, patient registries and other risk minimization tools.

In addition, if FDA or a comparable foreign regulatory authority approves one or more of our compounds, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for the approved drug will be subject to additional and potentially extensive ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration, as well as continued compliance with cGMPs and GCP requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our products, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- product seizure or detention, or refusal to permit the import or export of our products;
- injunctions or the imposition of civil or criminal penalties; and
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals.

The occurrence of any event or penalty described above may limit our ability to commercialize our compounds and generate revenue, and could require us to expend significant time and resources in response or generate negative publicity.

If any of our compounds are approved, our product labeling, advertising and promotion will also be subject to regulatory requirements and ongoing regulatory review. FDA strictly regulates the promotional claims that may be made about drug products. In particular, a drug may not be promoted for uses that are not approved by FDA as reflected in the drug's approved labeling. If we receive marketing approval for a compound, physicians may nevertheless lawfully prescribe it to their patients in a manner that is inconsistent with the approved label. While FDA recently clarified that mere knowledge that a physician is prescribing a drug for off label use is not sufficient to constitute unlawful off-label promotion, if we are found to have actively promoted such off label uses, we may become subject to significant

liability under the FDCA. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

FDA's and other regulatory authorities' policies are subject to change at any time, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our compounds. If we are unable to timely adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance post-marketing, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

Finally, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. It is difficult to predict how any such legislative, administrative or executive actions will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these legislative or executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

The COVID-19 coronavirus could adversely impact our business, including our clinical trials, and financial condition.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, the COVID-19 coronavirus has spread to multiple countries, including the United States, Australia and European and Asia-Pacific countries, including countries in which we have planned or active clinical trial sites. As the COVID-19 coronavirus continues to spread around the globe, we may experience disruptions that could potentially impact our business and clinical trials.

In addition, the spread of COVID-19 coronavirus has had and may continue to severely impact the trading price of shares of our common stock and could further severely impact our ability to raise additional capital on a timely basis or at all.

The global outbreak of the COVID-19 coronavirus continues to rapidly evolve. The extent to which the COVID-19 coronavirus may impact our future business operations, including our clinical trials, and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

Risks Related to our Common Stock

A decline in the price of our common stock could affect our ability to raise further working capital and adversely impact our operations and would severely dilute existing or future investors if we were to raise funds at lower prices.

A prolonged decline in the price of our common stock could result in a reduction in our ability to raise capital. Because our operations have been financed through the sale of equity securities, a decline in the price of our common stock could be especially detrimental to our continued operations. Any reduction in our ability to raise equity capital in the future would force us to reallocate funds from other planned uses and would have a significant negative effect on our business plans and operations, including our ability to develop new products and continue our current operations. If our stock price declines, there can be no assurance that we can raise additional capital or generate funds from operations sufficient to meet our obligations. We believe the following factors could cause the market price of our common stock to continue to fluctuate widely and could cause our common stock to trade at a price below the price at which you purchase your shares of common stock:

- actual or anticipated variations in our quarterly operating results;
- announcements of new services, products, acquisitions or strategic relationships by us or our competitors;
- changes in accounting treatments or principles;

- changes in earnings estimates by securities analysts and in analyst recommendations; and
- general political, economic, regulatory and market conditions.

The market price for our common stock may also be affected by our ability to meet or exceed expectations of analysts or investors. Any failure to meet these expectations, even if minor, could materially adversely affect the market price of our common stock.

If we issue additional shares of common stock in the future, it will result in the dilution of our existing stockholders and may cause the share price of our common stock to fall.

Our articles of incorporation authorize the issuance of 10,000,000 shares of preferred stock and 100,000,000 shares of common stock. Our board of directors has the authority to issue additional shares of preferred and common stock up to the authorized capital stated in the articles of incorporation. Our board of directors may choose to issue some or all such shares of common stock to acquire one or more businesses or to provide additional financing in the future. The issuance of any such shares of common stock will result in a reduction of the book value or market price of the outstanding shares of our common stock. If we do issue any such additional shares of common stock, such issuance also will cause a reduction in the proportionate ownership and voting power of all other stockholders. Further, any such issuance may result in a change of control of our corporation. In the event we do issue or sell additional shares of common or preferred stock, it may result in shareholder dilution and may cause our share price to fall.

Trading of our common stock may be volatile and sporadic, which could depress the market price of our common stock and make it difficult for our stockholders to resell their shares.

There is currently a limited market for our common stock and the volume of our common stock traded on any day may vary significantly from one period to another. Trading in our stock is often thin and characterized by wide fluctuations in trading prices, due to many factors that may have little to do with our operations or business prospects. The availability of buyers and sellers represented by this volatility could lead to a market price for our common stock that is unrelated to operating performance. There is no assurance that a sufficient market will develop in the stock, in which case it could be difficult for our stockholders to resell their stock.

The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

On June 7, 2019, we entered into a Purchase Agreement (the "2019 Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), as amended on July 1, 2020, pursuant to which Lincoln Park committed to purchase up to $50 million of our common stock. The purchase price for shares that we may sell to Lincoln Park under the 2019 Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

We have the right to control the timing and amount of any sales of our shares to Lincoln Park in our sole discretion, subject to certain limits on the amount of shares that can be sold on a given date. Sales of shares of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us. Therefore, Lincoln Park may ultimately purchase all, some or none of the shares of our common stock that may be sold pursuant to the 2019 Purchase Agreement and, after it has acquired shares, Lincoln Park may sell all, some or none of those shares. Sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales, which could have a materially adverse effect on our business and operations.

We may not be able to access sufficient funds under the 2019 Purchase Agreement or the Sales Agreement when needed.

Our ability to sell shares to Lincoln Park and obtain funds under the 2019 Purchase Agreement is limited by the terms and conditions in the 2019 Purchase Agreement, including restrictions on the amounts we may sell to Lincoln Park at any one time, and a limitation on our ability to sell shares to Lincoln Park to the extent that it would cause Lincoln

Park to beneficially own more than 4.99% of our outstanding shares of common stock. Additionally, the sale of common shares to Lincoln Park may be limited to a number of shares equal to 19.99% of the shares of common stock outstanding on the date of the amendment to the 2019 Purchase Agreement unless we obtain shareholder approval or the average price of such sales exceeds the price of our common stock on the amendment date of July 1, 2020 as determined under NASDAQ rules. At September 30, 2020, approximately $24.1 million in shares of our common stock remained available for purchase by Lincoln Park under the 2019 Purchase Agreement

In addition, on May 1, 2020, we entered into an Amended and Restated Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. and SVB Leerink LLC (the "Sales Agents") to offer shares of our common stock from time to time through "at-the-market" offerings, pursuant to which we may offer and sell shares of our common stock for an aggregate offering price of up to $50 million. While we have offered 1,760,429 shares of common stock through the Sales Agents pursuant to the Sales Agreement for gross proceeds of $7,499,900 through September 30, 2020 under the Sales Agreement, the Sales Agents are only obligated to act as our agent in the sale of shares pursuant to the Sales Agreement on a commercially reasonable efforts basis and subject to certain conditions set forth in the Sales Agreement.

Therefore, we may not in the future, have access to the full amount available to us under the Purchase Agreement or the Sales Agreement. In addition, any amounts we sell under the 2019 Purchase Agreement or the Sales Agreement may not satisfy all of our funding needs, even if we are able and choose to sell and issue all of our common stock currently registered.

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 that we may pursue may be impaired.

Our success depends in large part on our ability to obtain and maintain protection of our intellectual property, 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 our product candidates or by in-licensing intellectual property. U.S. patents related to ANAVEX®2-73 are directed to a dosage form comprising certain doses of ANAVEX®2-73 and donepezil, and the coverage is limited to the United States only. We may not be able to obtain patent protection for ANAVEX®2-73 as a single drug or in other jurisdictions.

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, or 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. 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 on 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.

In addition, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. 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. 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 patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

We hold ownership or exclusive rights to nine issued U.S. patent, ten U.S. patent applications, and various PCT or ex-U.S. patent applications relating to our drug candidates, methods associated therewith, and to our research programs. Neither patents nor patent applications ensure the protection of our intellectual property for a number of reasons, including the following:

1. Competitors may interfere with our patenting process in a variety of ways. Competitors may claim that Anavex is not entitled to an issued patent for a variety of legal reasons. Competitors may also claim that we are infringing their patents and restrict our freedom to operate. If a court or, in some circumstances, a board of a national patent authority, agrees, we would lose some or all of our patent protection. As a company, we have no meaningful experience with competitors interfering with our patents or patent applications.

2. Because of the time, money and effort involved in obtaining and enforcing patents, our management may spend less time and resources on developing potential drug compounds than they otherwise would, which could increase our operating expenses and delay product programs.

3. Issuance of a patent may not provide significant practical protection. If we receive a patent of narrow scope, then it may be possible for competitors to design products that do not infringe our patent(s).

4. Anavex is seeking patent protection for a number of indications, combination products and drug regimens. The lack of patent protection in global markets for a specific end product or indication may inhibit our ability to advance our compounds and may make Anavex less attractive to potential partners.

5. Defending a patent lawsuit takes significant time and can be very expensive.

6. If a court decides that an Anavex compound, its method of manufacture or use, infringes on the competitor's patent, we may have to pay substantial damages for infringement.

7. A court may prohibit us from making, selling or licensing the potential drug compound unless the patent holder grants a license. A patent holder is not required to grant a license. If a license is available, we may have to pay substantial royalties or grant cross licenses to our patents, and the license terms may be unacceptable.

8. Redesigning our potential drug compounds so that they do not infringe on other patents may not be possible or could require substantial funds and time.

It is also unclear whether our trade secrets are adequately protected. While we use reasonable efforts to protect our trade secrets, our employees or consultants may unintentionally or willfully disclose our information to competitors. Enforcing a claim that someone illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Our competitors may independently develop equivalent knowledge, methods and know-how.

We may also support and collaborate in research conducted by government organizations, hospitals, universities or other educational institutions. These research partners may be unable or unwilling to grant us exclusive rights to technology or products derived from these collaborations.

If we do not obtain required intellectual property licenses or rights, we could encounter delays in our product development efforts while we attempt to design around other patents or even be prohibited from developing, manufacturing or selling potential drug compounds requiring these rights or licenses. There is also a risk that legal disputes may arise as to the rights to technology or potential drug compounds developed in collaboration with other parties, all with attendant risk, distraction, expense, and lack of predictability.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or 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 an exclusive license agreement with Life Science Research Israel Ltd., with respect to certain in-licensed intellectual property related to our ANAVEX®3-71 product candidate, and we may need to obtain additional licenses from others in the future. Our license agreement with Life Science Research Israel Ltd. imposes, and we expect that

future license agreements will impose, various development, diligence, commercialization, 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. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of ANAVEX®3-71 or other product candidates covered by any such future licenses. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Moreover, 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.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. 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 relevant 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 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.

If we do not obtain required intellectual property licenses or rights, we could encounter delays in our product development efforts while we attempt to design around other patents or even be prohibited from developing, manufacturing or selling potential drug compounds requiring these rights or licenses. There is also a risk that legal disputes may arise as to the rights to technology or potential drug compounds developed in collaboration with other parties, all with attendant risk, distraction, expense, and lack of predictability.

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

Our success will also depend in part on our ability to commercialize our compounds without infringing the proprietary rights of others. We have not conducted extensive freedom of use patent searches and no assurance can be given that patents do not exist or could be issued which would have an adverse effect on our ability to market our technology or maintain our competitive position with respect to our technology. If our compounds or other subject matter are claimed under other United States patents or other international patents or are otherwise protected by third party proprietary rights, we may be subject to infringement actions. In such event, we may challenge the validity of such patents or other proprietary rights or we may be required to obtain licenses from such companies in order to develop, manufacture or market our technology. There can be no assurances that we would be successful in a challenge or be able to obtain such licenses or that such licenses, if available, could be obtained on commercially reasonable terms. Furthermore, the failure to succeed in a challenge, develop a commercially viable alternative or obtain needed licenses could be materially adverse. Adverse consequences include delays in marketing some or all of our potential drug compounds based on our drug technology or the inability to proceed with the development, manufacture or sale of potential drug compounds requiring such licenses. If we defend ourselves against charges of patent infringement or to protect our

proprietary rights against third parties, substantial costs will be incurred regardless of whether we are successful. Such proceedings are typically protracted with no certainty of success. An adverse outcome could subject us to significant liabilities to third parties and force us to curtail or cease the research and development of our technology.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize ANAVEX®2-73 or our other product candidates. 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. Additionally, 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.

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.

While we use reasonable efforts to protect our trade secrets, our employees or consultants may unintentionally or willfully disclose our information to competitors. Enforcing a claim that someone illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Our competitors may independently develop equivalent knowledge, methods and know-how.

We seek to protect our confidential proprietary information, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and collaborators. 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 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, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. 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.

Although we are not currently involved in any 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.

Competitors may infringe our patents or other intellectual property. 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 ANAVEX®2-73 or our other product candidates, 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 ANAVEX®2-73 or our other product candidates to market.

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.

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 firm and rely on our outside counsel to pay these fees due to 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 law firms and other 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. 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We do not own any real property. We maintain several offices of which the office at 7th Floor, 51 West 52nd Street, New York, NY, USA is our main office. Our lease costs are approximately $20,000 per month. We believe our offices are suitable and adequate to operate our business now as they provide us with sufficient space to conduct our operations. We fully utilize our current premises.

ITEM 3. LEGAL PROCEEDINGS

We know of no material pending legal proceedings, other than ordinary routine litigation incidental to our business, to which our Company or our subsidiary is a party or of which any of their property is subject. There are no proceedings in which any of our directors, officers or affiliates, or any registered or beneficial stockholder holding more than 5% of our shares, is an adverse party or has a material interest adverse to our or our subsidiary's interest.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market information

Our common stock is quoted on the NASDAQ Stock Market LLC ("NASDAQ") under the symbol "AVXL."

Holders of Common Stock

As of December 28, 2020, there were approximately 53 holders of record and 66,962,957 shares of our common stock were issued and outstanding.

Dividends

We have not paid any cash dividends on our common stock and have no intention of paying any dividends on the shares of our common stock. Our current policy is to retain earnings, if any, for use in our operations and in the development of our business. Our future dividend policy will be determined from time to time by our board of directors.

Recent Sales of Unregistered Securities

Since the beginning of our fiscal year ended September 30, 2020, we have not sold any equity securities that were not registered under the Securities Act of 1933 that were not previously reported in a quarterly report on Form 10-Q or in a current report on Form 8-K.

Repurchases of Equity Securities by Our Company and Affiliated Purchasers

None.

ITEM 6 SELECTED FINANCIAL DATA

Not applicable.

ITEM 7 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

The following discussion should be read in conjunction with our audited consolidated financial statements and notes thereto for the fiscal year ended September 30, 2020, included elsewhere in this Annual Report on Form 10-K.

Financial Highlights

During fiscal 2020, we made significant progress in the advancement of clinical studies for ANAVEX®2-73, including continued enrollment of our Phase 2b/3 Alzheimer's disease trial and expansion of this trial internationally, completion of our proof-of-concept Phase 2 Parkinson's disease dementia trial, continued advancement of a multi-regional Phase 2/3 clinical program for the treatment of Rett syndrome, including completion of the Phase 2 U.S. trial and expansion of the AVATAR Phase 2 study internationally and the commencement of the EXCELLENCE Phase 2/3 pediatric Rett syndrome study. While fiscal 2020 was marked by the outbreak of COVID-19, which temporarily slowed down activities in many of the countries in which these trials are taking place, our clinical trials were able to continue largely uninterrupted in compliance with local regulations and policies, and we were able to continue to recruit and screen new patients as much as possible to advance these studies. Additionally, we commenced the first in human Phase 1 clinical trial of ANAVEX®3-71 during fiscal 2020 with focus on the treatment of Frontotemporal Dementia (FTD) and other dementia indications with unmet medical need.

As a result, our operating expenses for fiscal 2020 increased to $31.1 million, from $29.1 million in fiscal 2019, an increase of approximately 6.9%. The increase is attributable to an increase in research and development expenses of $2.9 million in 2020 to $25.2 million, or approximately 13.3%.

During fiscal 2020, we utilized $21.3 million to fund our operations, compared to $18.5 million during fiscal 2019. Our cash position increased to $29.2 million at September 30, 2020. Our operations were financed through the issuance of shares of common stock under the 2019 Purchase Agreement, and the Sales Agreement.

We continue to see an increase in our research and development expenditures as we advance our ANAVEX®2-73 clinical studies, including adding extension studies to allow us to continue to gather longer term data, and adding additional staffing to manage the clinical studies currently underway. We also continue to receive support from the Australian government for various clinical trials being conducted within Australia. We will continue to target potential research partners to further advance our pipeline compounds.

In August 2020, we announced a financial commitment by Shake It Up Australia Foundation (SIUAF) for Parkinson's Research to fund up to 50% of the costs of an Australian clinical study to develop ANAVEX®2-73 for the disease modifying treatment of Parkinson's disease. The financial commitment would be made through private placement purchases of our common stock at 200% of the fair market value on the purchase date and will be contingent upon the completion of certain clinical trial milestones relating to the proposed clinical trial. There was no impact on our consolidated financial statements for the year ended September 30, 2020 as a result of the commitment from SIUAF.

Net loss for fiscal 2020 was $26.3 million, or $0.45 per share, as compared to $26.3 million, or $0.54 per share in fiscal 2019.

Results of Operations

Revenue

We are in the development stage and have not earned any revenues since our inception. We do not anticipate earning any revenues until we can establish an alliance with other companies to develop, co-develop, license, acquire or market our products.

Year ended September 30, 2020 compared to year ended September 30, 2019

Operating Expenses

Total operating expenses for the year ended September 30, 2020 were $31.1 million, compared to $29.1 million in fiscal 2019, which was an increase of approximately $2.0 million from fiscal 2019, or 6.9%.

Research and development expenses for fiscal 2020 were $25.2 million, as compared to $22.3 million fiscal 2019, an increase of $2.9 million, or approximately 13.3%. The largest reason for this increase is due to continued advancement, enrollment and expansion of the company's clinical trials with ANAVEX®2-73, the commencement of clinical trials for ANAVEX®3-71 and expanded clinical development staffing.

During fiscal 2020 our general and administrative expenses were $5.9 million as compared to $6.8 million in fiscal 2019, a decrease of $0.9 million, primarily related to decreased stock-option compensation charges of $1.0 million.

Other income

The net amount of other income for the year ended September 30, 2020 was $4.8 million as compared to $2.9 million for fiscal 2019. During fiscal 2020, we recorded $4.4 million in research and development incentive income, including the Australian research and development incentive credit administered through the Australian Tax Office, in connection with fiscal 2020 eligible expenditures and fiscal 2019 expenditures for which an overseas finding ruling was obtained during the current year. In comparison, research and development incentive income for fiscal 2019 was $2.5 million in connection with fiscal 2019 eligible expenditures.

Net loss for fiscal 2020 was $26.3 million, or $0.45 per share, compared to a net loss of approximately $26.3 million, or $0.54 per share for fiscal 2019.

Liquidity and Capital Resources

Working Capital

	2020	2019
Current Assets	$ 34,542,197	$ 25,329,373
Current Liabilities	7,305,628	5,039,674
Working Capital	$ 27,236,569	$ 20,289,699

At September 30, 2020, we had $29.2 million in cash and cash equivalents, an increase of $7.0 million, from $22.2 million at September 30, 2019. The principal reason for this increase is due to net cash received from financing activities of $28.4 million from the issuance of common shares, offset by cash utilized in operations of $21.3 million.

We intend to continue to use our capital resources to advance our clinical trials for ANAVEX®2-73, and to perform work necessary to prepare for future development of our pipeline compounds.

Cash Flows

	2020	2019
Cash flows used in operating activities	$ (21,287,046)	$ (18,527,117)
Cash flows provided by financing activities	28,350,434	17,782,109
Increase (decrease) in cash	$ 7,063,388	$ (745,008)

Cash flow used in operating activities

There was an increase in cash used in operating activities of $2.8 million during fiscal 2020 due to an increase in clinical trial activities, as more fully described above.

Cash flow provided by financing activities

Cash provided by financing activities for fiscal 2020 was related to cash received from the issuance of shares under the 2019 Purchase Agreement and the Sales Agreement, as more fully described below. During fiscal 2020, we issued an aggregate of 9.4 million shares for gross proceeds of $28.8 million. During fiscal 2019, we issued an aggregate of 6.7 million shares for gross proceeds of $17.8 million.

Other Financings

Purchase Agreement

On June 7, 2019, we entered into a Purchase Agreement (the "2019 Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), as amended on July 1, 2020, pursuant to which Lincoln Park committed to purchase up to $50,000,000 of our common stock. Concurrently with the execution of the 2019 Purchase Agreement in 2019, we issued 324,383 shares of our common stock to Lincoln Park as a fee for its commitment to purchase shares of our common stock under the 2019 Purchase Agreement and shall issue up to 162,191 shares pro rata, when and if Lincoln Park purchases, at our discretion, the $50,000,000 aggregate commitment. The purchase shares that may be sold pursuant to the 2019 Purchase Agreement may be sold by us to Lincoln Park at our discretion from time to time until July 1, 2022.

We may direct Lincoln Park, at our sole discretion, and subject to certain conditions, to purchase up to 200,000 shares of common stock on any business day (a "Regular Purchase"). The amount of a Regular Purchase may be increased under certain circumstances up to 250,000 shares provided that Lincoln Park's committed obligation for Regular Purchases on any business day shall not exceed $2,000,000. In the event we purchase the full amount allowed for a Regular Purchase on any given business day, we may also direct Lincoln Park to purchase additional amounts as accelerated and additional purchases. The purchase price of shares of common stock related to the future funding will be based on the then prevailing market prices of such shares at the time of sales as described in the 2019 Purchase Agreement.

At September 30, 2020, approximately $24.1 million in shares of our common stock remained available for purchase by Lincoln Park under the 2019 Purchase Agreement.

Controlled Equity Offering Sales Agreement

On May 1, 2020, we entered into an Amended and Restated Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. and SVB Leerink LLC (the "Sales Agents"), pursuant to which we may offer and sell shares of common stock, for aggregate gross sale proceeds of up to $50,000,000 from time to time through the Sales Agents (the "At-the-Market Offering").

Upon delivery of a placement notice based on our instructions and subject to the terms and conditions of the Sales Agreement, the Sales Agents may sell shares of common stock by methods deemed to be an "at the market offering", in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, or by any other method permitted by law, including negotiated transactions, subject to our prior written consent. We are not obligated to make any sales of shares under the Sales Agreement. We or the Sales Agents may suspend or terminate the At-the-Market Offering upon notice to the other party, subject to certain conditions. The Sales Agents will act as agents on a commercially reasonable efforts basis consistent with their normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of Nasdaq.

We have agreed to pay the Sales Agents commissions for their services of 3.0% of the gross proceeds from the sale of the Shares pursuant to the Sales Agreement. We have also agreed to provide the Sales Agents with customary indemnification and contribution rights. At September 30, 2020, an amount of $42.5 million remained available under the Sales Agreement.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to our stockholders.

APPLICATION OF CRITICAL ACCOUNTING POLICIES

Our financial statements and accompanying notes are prepared in accordance with generally accepted accounting principles in the United States. Preparing financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses. These estimates and assumptions are affected by management's application of accounting policies. We believe that understanding the basis and nature of the estimates and assumptions involved with the following aspects of our financial statements is critical to an understanding of our financial statements.

We base our assumptions and estimates on historical experience and other sources that we believe to be reasonable at the time. Actual results may vary from our estimates due to changes in circumstances, politics, global economics, general business conditions and other factors. Our significant estimates are related to the valuation of warrants and options.

There are accounting policies that we believe are significant to the presentation of our financial statements. The most significant of these accounting policies relates to the accounting for our research and development expenses and stock-based compensation expense.

Research and Development Expenses

Research and development costs are expensed as incurred. These expenses are comprised of the costs of the Company's proprietary research and development efforts, including preclinical studies, clinical trials, manufacturing costs, employee salaries and benefits and stock based compensation expense, contract services including external research and development expenses incurred under arrangements with third parties such as contract research organizations ("CROs"), facilities costs, overhead costs and other related expenses. Milestone payments made by the Company to third parties are expensed when the specific milestone has been achieved. Manufacturing costs are expensed as incurred in accordance with Accounting Standard Codification ("ASC") 730, Research and Development, as these materials have no alternative future use outside of their intended use.

Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and amortized over the period that the goods are delivered, or the related services are performed, subject to an assessment of recoverability. The Company makes estimates of costs incurred in relation to external CROs, and clinical site costs. The Company analyzes the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued balance and expense in any accounting period. The Company reviews and accrues CRO expenses and clinical trial study expenses based on work performed and relies upon estimates of those costs applicable to the stage of completion of a study. Accrued CRO costs are subject to revisions as such trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. With respect to clinical site costs, the financial terms of these agreements are subject to negotiation and vary from contract to contract. Payments under these contracts may be uneven and depend on factors such as the achievement of certain events, the successful recruitment of patients, the completion of portions of the clinical trial or similar conditions. The objective of our policy is to record expenses in our financial statements based on actual services received and efforts expended. As such, expense accruals related to clinical site costs are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

In addition, we incur expenses in respect of patents and trademarks. The probability of success and length of time to develop commercial applications of the compounds subject to the underlying patents and trademarks is difficult to determine and numerous risks and uncertainties exist with respect to the timely completion of the development projects. There is no assurance the compounds subject to the underlying patents and trademarks will ever be successfully commercialized. Due to these risks and uncertainties, we expense the patent and trademark costs within general and administrative expenses in our financial statements.

Stock-based Compensation

We account for all stock-based payments and awards under the fair value-based method.

We account for the granting of share purchase options and warrants to employees using the fair value method whereby all awards to employees will be recorded at fair value on the date of the grant. The fair value of all share purchase options and warrants are expensed over their contractual vesting period, or over the expected performance period for only the portion of awards expected to vest, in the case of milestone-based vesting, with a corresponding increase to additional paid-in capital.

Share purchase options and warrants issued to non-employees are measured at the fair value of the equity instruments issued. Compensation expense for share purchase options and warrants issued to non-employees is recorded over the service performance period. Prior to our adoption of ASU No. 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting on October 1, 2019, options and warrants subject to vesting were periodically re-measured until the counterparty performance was complete, and any change therein was recognized over the vesting period of the award and in the same manner as if we had paid cash instead of paying with or using equity based instruments. After the adoption of ASU No. 2018-07, we measure equity-classified share-based payment awards issued to nonemployees on the grant date, rather than remeasuring the awards through the performance completion date as previously required.

Compensation costs for stock-based payments with graded vesting are recognized on a straight-line basis.

We use the Black-Scholes option valuation model to calculate the fair value of share purchase options and warrants at the date of the grant. Option pricing models require the input of highly subjective assumptions, including the expected price volatility. Changes in these assumptions can materially affect the fair value estimates.

For a discussion of recent accounting pronouncements and their possible effect on our results, see Note 2(n) to our Consolidated Financial Statements found elsewhere in this Annual Report.

ITEM 7A QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ANAVEX LIFE SCIENCES CORP.

CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2020

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Anavex Life Sciences Corp.
New York, New York

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Anavex Life Sciences Corp. and subsidiaries (the "Company") as of September 30, 2020 and 2019, the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the years in the period ended September 30, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at September 30, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2013.

New York, New York
December 28, 2020

ANAVEX LIFE SCIENCES CORP.
CONSOLIDATED BALANCE SHEETS
As at September 30, 2020 and 2019

	2020	2019
Assets		
Current		
Cash and cash equivalents	$ 29,249,018	$ 22,185,630
Incentive and tax receivables	4,849,340	2,642,745
Prepaid expenses and deposits	443,839	500,998
Total Assets	$ 34,542,197	$ 25,329,373
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 3,989,054	$ 3,523,332
Accrued liabilities	3,316,574	1,516,342
Total Liabilities	7,305,628	5,039,674
Commitments and Contingencies - Note 5		
Capital stock=		
Authorized:		
10,000,000 preferred stock, par value $0.001 per share		
100,000,000 common stock, par value $0.001 per share		
Issued and outstanding:		
62,045,198 common shares (2019 - 52,650,521)	62,047	52,652
Additional paid-in capital	186,851,752	153,633,807
Accumulated deficit	(159,677,230)	(133,396,760)
Total Stockholders' Equity	27,236,569	20,289,699
Total Liabilities and Stockholders' Equity	$ 34,542,197	$ 25,329,373

See Accompanying Notes to Consolidated Financial Statements

ANAVEX LIFE SCIENCES CORP.
CONSOLIDATED STATEMENTS OF OPERATIONS
For the years ended September 30, 2020 and 2019

	2020	2019
Operating expenses		
General and administrative	$ 5,856,609	$ 6,846,599
Research and development	25,231,623	22,260,349
Total operating expenses	(31,088,232)	(29,106,948)
Other income (expenses)		
Grant income	149,888	298,943
Research and development incentive income	4,375,025	2,465,691
Interest income, net	179,973	207,280
Gain on settlement of accounts payable	—	115,758
Financing related charges	—	(151,133)
Foreign exchange gain (loss), net	125,540	(42,389)
Total other income, net	4,830,426	2,894,150
Net loss before provision for income taxes	(26,257,806)	(26,212,798)
Income tax expense, current	(22,664)	(82,181)
Net loss and comprehensive loss	$ (26,280,470)	$ (26,294,979)
Net Loss per share		
Basic and diluted	$ (0.45)	$ (0.54)
Weighted average number of shares outstanding		
Basic and diluted	58,194,894	48,906,470

See Accompanying Notes to Consolidated Financial Statements

ANAVEX LIFE SCIENCES CORP.
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the years ended September 30, 2020 and 2019

	2020	2019
Cash Flows used in Operating Activities		
Net loss	$ (26,280,470)	$ (26,294,979)
Adjustments to reconcile net loss to net cash used in operations:		
Stock-based compensation	4,876,906	6,430,873
Deferred costs	—	151,133
Gain on settlement of accounts payable	—	(115,758)
Changes in non-cash working capital balances related to operations:		
Incentive and tax receivables	(2,206,595)	(772,388)
Prepaid expenses and deposits	57,159	803,196
Accounts payable	465,722	683,797
Accrued liabilities	1,800,232	587,009
Net cash used in operating activities	(21,287,046)	(18,527,117)
Cash Flows provided by Financing Activities		
Issuance of common shares	28,754,198	17,832,109
Share issue costs	(403,764)	—
Deferred financing charges	—	(50,000)
Net cash provided by financing activities	28,350,434	17,782,109
Increase (decrease) in cash and cash equivalents during the period	7,063,388	(745,008)
Cash and cash equivalents, beginning of year	22,185,630	22,930,638
Cash and cash equivalents, end of year	$ 29,249,018	$ 22,185,630

See Accompanying Notes to Consolidated Financial Statements

ANAVEX LIFE SCIENCES CORP.

CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

For the years ended September 30, 2020 and 2019

	Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance, September 30, 2018	45,933,472	45,935	$ 129,377,542	$ (107,101,781)	$ 22,321,696
Shares issued under 2015 Purchase Agreement					
Purchase shares	4,848,995	4,849	13,192,755	—	13,197,604
Commitment shares	23,701	24	(24)	—	—
Shares issued under 2019 Purchase Agreement					
Purchase shares	1,500,000	1,500	4,633,005	—	4,634,505
Commitment shares	339,415	339	(339)		
Shares issued pursuant to cashless exercise of warrants	4,938	5	(5)	—	—
Share based compensation	—	—	6,430,873	—	6,430,873
Net loss	—	—	—	(26,294,979)	(26,294,979)
Balance, September 30, 2019	52,650,521	52,652	$ 153,633,807	$ (133,396,760)	$ 20,289,699
Shares issued under 2019 Purchase Agreement					
Purchase shares	7,564,584	7,565	21,246,733	—	21,254,298
Commitment shares	68,943	69	(69)	—	—
Shares issued pursuant to cashless exercise of options	721	1	(1)	—	—
Shares issued under Sales Agreement, net of shares issue costs	1,760,429	1,760	7,094,376		7,096,136
Share based compensation	—	—	4,876,906	—	4,876,906
Net loss	—	—	—	(26,280,470)	(26,280,470)
Balance, September 30, 2020	62,045,198	62,047	$ 186,851,752	$ (159,677,230)	$ 27,236,569

See Accompanying Notes to Consolidated Financial Statements

Note 1 Business Description and Basis of Presentation

Business

Anavex Life Sciences Corp. ("Anavex" or the "Company") is a clinical stage biopharmaceutical company engaged in the development of differentiated therapeutics by applying precision medicine to central nervous system ("CNS") diseases with high unmet need. Anavex analyzes genomic data from clinical studies to identify biomarkers, which are used to select patients that will receive the therapeutic benefit for the treatment of neurodegenerative and neurodevelopmental diseases. The Company's lead compound ANAVEX®2-73 is being developed to treat Alzheimer's disease, Parkinson's disease and potentially other central nervous system diseases, including rare diseases, such as Rett syndrome, a rare severe neurological monogenic disorder caused by mutations in the X-linked gene, methyl-CpG-binding protein 2 ("MECP2").

Basis of Presentation

These consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") and the instructions to Form 10-K and have been prepared under the accounting principles generally accepted in the United States of America ("U.S. GAAP").

Liquidity

All of the Company's potential drug compounds are in the clinical development stage and the Company cannot be certain that its research and development efforts will be successful or, if successful, that its potential drug compounds will ever be approved for sales to pharmaceutical companies or generate commercial revenues. To date, we have not generated any revenues from our operations. The Company expects the business to continue to experience negative cash flows for the foreseeable future and cannot predict when, if ever, our business might become profitable.

The Company believes that its existing cash and cash equivalents, along with existing financial commitments from third parties, will be sufficient to meet its cash commitments for in excess of two years after the date that these consolidated financial statements are issued. The process of drug development can be costly, and the timing and outcomes of clinical trials is uncertain. The assumptions upon which the Company has based its estimates are routinely evaluated and may be subject to change. The actual amount of the Company's expenditures will vary depending upon a number of factors including but not limited to the design, timing and duration of future clinical trials, the progress of the Company's research and development programs and the level of financial resources available. The Company has the ability to adjust its operating plan spending levels based on the timing of future clinical trials.

Other than our rights related to the 2019 Purchase Agreement and the Sales Agreement (each as defined below in Note 4), there can be no assurance that additional financing will be available to us when needed or, if available, that it can be obtained on commercially reasonable terms. If the Company is not able to obtain the additional financing on a timely basis, if and when it is needed, it will be forced to delay or scale down some or all of its research and development activities.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. In March 2020, the World Health Organization ("WHO") declared COVID-19 to be a global pandemic as a result of the rapid spread of the virus beyond its point of origin.

The global outbreak of COVID-19 continues to rapidly evolve as of the date these consolidated financial statements are issued. As such, it is uncertain as to the full magnitude that the outbreak will have on the Company's financial condition and future results of operations. Management is actively monitoring the global situation on its business, including on its clinical trials and operations and financial condition. The effects of COVID-19 did not have a material impact on the Company's result of operations or financial condition for the year ended September 30, 2020. However, given the daily evolution of the COVID-19 situation, and the global responses to curb its spread, the Company is not able to estimate the effects COVID-19 may have on its future results of operations or financial condition.

On March 27, 2020, the President of the United States signed into law the "Coronavirus Aid, Relief, and Economic Security (CARES) Act." The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations, increased limitations on qualified charitable contributions, and technical corrections to tax depreciation methods for qualified improvement property. The enactment of the CARES Act did not have any material impact on the Company's consolidated financial statements or deferred tax assets or liabilities.

Note 2 Summary of Significant Accounting Policies

a) Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses in the reporting period. The Company regularly evaluates estimates and assumptions related to accounting for research and development costs, incentive income receivable, valuation and recoverability of deferred tax assets, asset impairment, stock-based compensation and loss contingencies. The Company bases its estimates and assumptions on current facts, historical experience and various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the book values of assets and liabilities and the accrual of costs and expenses that are not readily apparent from other sources. The actual results experienced by the Company may differ materially and adversely from the Company's estimates. To the extent there are material differences between the estimates and the actual results, future results of operations will be affected.

b) Principles of Consolidation

These consolidated financial statements include the accounts of Anavex Life Sciences Corp. and its wholly-owned subsidiaries, Anavex Australia Pty Limited. ("Anavex Australia"), a company incorporated under the laws of Australia, Anavex Germany GmbH, a company incorporated under the laws of Germany, and Anavex Canada Ltd., a company incorporated under the laws of the Province of Ontario, Canada. All inter-company transactions and balances have been eliminated.

c) Cash and equivalents

The Company considers only those investments which are highly liquid, readily convertible to cash and that mature within three months from the date of purchase to be cash equivalents.

d) Research and Development Expenses

Research and development costs are expensed as incurred. These expenses are comprised of the costs of the Company's proprietary research and development efforts, including preclinical studies, clinical trials, manufacturing costs, employee salaries and benefits and stock based compensation expense, contract services including external research and development expenses incurred under arrangements with third parties such as contract research organizations ("CROs"), facilities costs, overhead costs and other related expenses. Milestone payments made by the Company to third parties are expensed when the specific milestone has been achieved. Manufacturing costs are expensed as incurred in accordance with Accounting Standard Codification ("ASC") 730, Research and Development, as these materials have no alternative future use outside of their intended use.

Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and amortized over the period that the goods are delivered, or the related services are performed, subject to an assessment of recoverability. The Company makes estimates of costs incurred in relation to external CROs, and clinical site costs. The Company analyzes the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued balance and expense in any accounting period. The Company reviews and accrues CRO expenses and clinical trial study expenses based on work performed and relies upon estimates of those costs applicable to the stage of completion of a study. Accrued CRO costs are subject to revisions as such trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. With respect to clinical site costs, the financial terms of these agreements are subject to negotiation and vary from contract to contract. Payments under these contracts may be uneven and depend on factors such as the achievement of certain events, the successful recruitment of patients, the completion of portions of the clinical trial or similar conditions. The objective of our policy is to record expenses in our financial statements based on the actual services received and efforts expended. As such, expense accruals related to clinical site costs are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

In addition, the Company incurs expenses in respect of intellectual property costs relating to patents and trademarks. The probability of success and length of time to develop commercial applications of the compounds subject to the

underlying patent and trademark costs is difficult to determine and numerous risks and uncertainties exist with respect to the timely completion of the development projects. There is no assurance the compounds subject to the underlying patents and trademarks will ever be successfully commercialized.

Due to these risks and uncertainties, the patent and trademark costs do not meet the definition of an asset and thus are expensed as incurred within general and administrative expenses.

e) Research and Development Incentive Income

The Company is eligible to obtain certain research and development tax credits, including the New York City Biotechnology Tax Credit ("NYC Biotech credit"), and the Australian research and development tax incentive credit (the "Australia R&D credit") through a program administered through the Australian Tax Office (the "ATO"), which provides for a cash refund based on a percentage of certain research and development activities undertaken in Australia by the Company's wholly owned subsidiary, Anavex Australia Pty Ltd. ("Anavex Australia"). The cash refund is available to eligible companies with an annual aggregate revenue of less than $20.0 million Australian during the reimbursable period.

The tax incentives are available on the basis of specific criteria with which the Company must comply. Although the tax incentive may be administered through the local tax authority, the Company has accounted for the incentives outside of the scope of ASC Topic 740, Income Taxes ("ASC 740"), since the incentives are not linked to the Company's taxable income and can be realized regardless of whether the Company has generated taxable income in the respective jurisdictions.

With respect to the Australia R&D credit, Anavex Australia may be eligible to receive the cash refund for certain research and development expenses incurred by Anavex Australia outside of Australia, to the extent such expenses are pre-approved by the Australian authority pursuant to an advanced overseas finding application. The Company accrues for the amount of cash refund it expects to receive in relation to research and development expenses outside of Australia only to the extent it has received advanced approval from the Department of Industry, Innovation and Science in Australia, pursuant to an approved advanced overseas finding application.

The Company recognizes the amount of cash refund it expects to receive related to the NYC Biotech credit and Australian research and development tax incentive program when there is reasonable assurance that the cash refund will be received, when the relevant expenditures have been incurred, and when the amount can be reliably measured. This amount is included in Incentive and tax receivables in the accompanying consolidated balance sheets.

In addition, Anavex Australia and Anavex Canada incur Goods and Services Tax (GST) on certain services provided by local vendors. As a domestic entity in those jurisdictions, Anavex Australia and Anavex Canada are entitled to a refund of the GST paid. Similarly, Anavex Germany incurs Value Added Tax (VAT) on certain services provided by local vendors, to which it is entitled to a refund of such VAT paid. The Company's estimate of the amount of cash refund it expects to receive related to GST and VAT incurred is included in Incentive and tax receivables in the accompanying consolidated balance sheets.

f) Basic and Diluted Loss per Share

Basic income/(loss) per common share is computed by dividing net income/(loss) available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted income/(loss) per common share is computed by dividing net income/(loss) available to common stockholders by the sum of (1) the weighted-average number of common shares outstanding during the period, (2) the dilutive effect of the assumed exercise of options and warrants using the treasury stock method and (3) the dilutive effect of other potentially dilutive securities. For purposes of the diluted net loss per share calculation, options and warrants are potentially dilutive securities and are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive.

As of September 30, 2020, diluted loss per share excludes 10,576,266 (2019 – 8,812,933) potentially dilutive common shares related to outstanding options and warrants, as their effect was anti-dilutive.

g) Financial Instruments

The book value of the Company's financial instruments, consisting of cash and equivalents, incentive and tax receivables, and accounts payable and accrued liabilities approximate their fair value due to the short-term maturity of such instruments. Unless otherwise noted, it is management's opinion that the Company is not exposed to significant interest, currency or credit risks arising from these financial instruments.

h) Foreign Currency Translation

The functional currency of the Company is the US dollar. Monetary items denominated in a foreign currency are translated into US dollars at exchange rates prevailing at the balance sheet date and non-monetary items are translated at exchange rates prevailing when the assets were acquired, or obligations incurred. Foreign currency denominated expense items are translated at exchange rates prevailing on the transaction date. Unrealized gains or losses arising from the translations are credited or charged to income in the period in which they occur.

The Company has determined that the functional currency of Anavex Australia Pty Limited, Anavex Germany GmbH, and Anavex Canada Ltd. is the US dollar.

i) Segment and Geographic Reporting

Operating segments are defined as components of an enterprise for which separate discrete information is available for evaluation by the chief operating decision maker or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business as one operating segment, which is the business of developing novel therapies for the management of CNS diseases.

j) Grant Income

Grant income is recognized at the fair value of the grant when it is received, and all substantive conditions have been satisfied. Grants received from government and other agencies in advance of the specific research and development costs to which they relate are deferred and recognized in the consolidated statement of operations in the period they are earned and when the related research and development costs are incurred.

k) Income Taxes

The Company follows the provisions of ASC 740, which requires the asset and liability method of accounting for income taxes. Under the asset and liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statements carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

The Company follows the provisions of ASC 740 regarding accounting for uncertainty in income taxes. The Company initially recognizes tax positions in the financial statements when it is more likely than not the position will be sustained upon examination by the tax authorities. Such tax positions are initially and subsequently measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement with the tax authority assuming full knowledge of the position and all relevant facts. Application requires numerous estimates based on available information. The Company considers many factors when evaluating and estimating its tax positions and tax benefits, and its recognized tax positions and tax benefits may not accurately anticipate actual outcomes. As additional information is obtained, there may be a need to periodically adjust the recognized tax positions and tax benefits. These periodic adjustments may have a material impact on the consolidated statements of operations.

The Company recognizes interest and penalties related to current income tax expense on the interest income, net line, in the accompanying consolidated statement of operations. Accrued interest and penalties, if any, are included in accrued liabilities on the consolidated balance sheets.

l) Stock-based Compensation

The Company accounts for all stock-based payments and awards under the fair value method.

The Company accounts for the granting of share purchase options and warrants to employees using the fair value method whereby all awards to employees will be recorded at fair value on the date of the grant. The fair value of

all share purchase options and warrants are expensed over their contractual vesting period, or over the expected performance period for only the portion of awards expected to vest, in the case of milestone-based vesting, with a corresponding increase to additional paid-in capital.

Share purchase options and warrants issued to non-employees are measured at the fair value of the equity instruments issued. Compensation expense for share purchase options and warrants issued to non-employees is recorded over the service performance period. Prior to the Company's adoption of ASU No. 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting on October 1, 2019, options and warrants subject to vesting were periodically re-measured until the counterparty performance was complete, and any change therein was recognized over the vesting period of the award and in the same manner as if the Company had paid cash instead of paying with or using equity based instruments. After the adoption of ASU No. 2018-07, the Company measures equity-classified share-based payment awards issued to nonemployees on the grant date, rather than remeasuring the awards through the performance completion date as previously required (see Note 2 n)).

Compensation costs for stock-based payments with graded vesting are recognized on a straight-line basis.

The Company uses the Black-Scholes option valuation model to calculate the fair value of share purchase options and warrants at the date of the grant. Option pricing models require the input of highly subjective assumptions, including the expected price volatility. Changes in these assumptions can materially affect the fair value estimates.

m) Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. Assets and liabilities that are measured at fair value are reported using a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

Level 1 - quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date;

Level 2 - observable inputs other than Level 1, quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, and model-derived prices whose inputs are observable or whose significant value drivers are observable; and

Level 3 - assets and liabilities whose significant value drivers are unobservable by little or no market activity and that are significant to the fair value of the assets or liabilities.

At September 30, 2020 and 2019, the Company did not have any Level 3 assets or liabilities.

n) Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In February 2016, Topic 842, Leases was issued to replace the leases requirements in Topic 840, Leases. The main difference between previous U.S. GAAP and Topic 842 is the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous U.S. GAAP. A lessee should recognize in the balance sheet a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. If a lessee makes this election, it should recognize lease expense for such leases generally on a straight-line basis over the lease term. The accounting applied by a lessor is largely unchanged from that applied under previous U.S. GAAP. The Company elected the package of practical expedients permitted under the transition guidance that allowed, among other things, the historical lease classifications to be carried forward without reassessment. Further, the Company elected to not recognize lease assets and lease liabilities for leases with a term of 12 months or less. The adoption of this standard on October 1, 2019 did not have any impact on the Company's consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

Note 2 Summary of Significant Accounting Policies (continued)

In June 2018, the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, which simplifies the accounting for share-based payments to nonemployees for goods and services by aligning it with the accounting for share-based payments to employees, with certain exceptions. The new guidance was effective for the Company beginning on October 1, 2019 and was required to be applied retrospectively with the cumulative effect recognized at the date of initial application. The adoption of this standard on October 1, 2019 did not have any material impact on the Company's consolidated results of operations, financial condition, cash flows, and financial statement disclosures.

Recent Accounting Pronouncements Not Yet Adopted

In December 2019, the FASB issued ASU 2019-12, "Simplifying the Accounting for Income Taxes (ASC 740)", which is intended to simplify various aspects related to accounting for income taxes by removing certain exceptions to the general principles in Topic 740 and clarifying and amending existing guidance to improve consistent application. ASU 2019-12 is effective for the Company on October 1, 2021. Early adoption is permitted. The Company is currently evaluating the impact of this guidance on its consolidated financial statements but does not expect such guidance to have a material impact.

Note 3 Other Income

Grant income

During the year ended September 30, 2017, the Company was awarded grant funding in the amount of $597,886. The grant was received in equal quarterly installments over a period of two years ending during the year ended September 30, 2020, in exchange for a commitment to complete clinical testing for a therapeutic drug candidate for the treatment of Rett syndrome.

The grant income was deferred when received and amortized to other income as the related research and development expenditures were incurred. During the year ended September 30, 2020, the Company recognized $149,888 (2019: $298,943) of this grant on its statement of operations as a component of other income. At September 30, 2020, the Company had recognized the full amount of grant funding.

Research and development incentive income

Research and development incentive income during the years ended September 30, 2020 and 2019 represents the receipt by Anavex Australia, of the Australia R&D Credit, as well as receipt by the Company of the New York City Biotechnology Credit ("NYC Biotech credit").

During the year ended September 30, 2020, the Company recorded research and development incentive income of $4,375,025 (AUD 6,392,266) (2019: $2,215,691 (AUD 3,281,300)) in respect of the Australia R&D Credit for eligible research and development expenses incurred during the year, or expenditures to which the Company became eligible during the year.

During the year ended September 30, 2019, the Company recorded research and development incentive income of $250,000 in respect of the NYC Biotech Credit. The Company was no longer eligible for the NYC Biotech Credit for the fiscal year ended September 30, 2020.

Note 4 Equity Offering Agreements

2015 Purchase Agreement

On October 21, 2015, the Company entered into a $50,000,000 purchase agreement (the "2015 Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which the Company could sell and issue to Lincoln Park, and Lincoln Park was obligated to purchase, up to $50,000,000 in value of its shares of common stock from time to time over a 36-month period.

During the year ended September 30, 2019, the Company issued to Lincoln Park an aggregate of 4,872,696 shares of common stock under the 2015 Purchase Agreement, including 4,848,995 shares of common stock for an aggregate purchase price of $13,197,604 and 23,701 as commitment shares. At September 30, 2019, all remaining purchase

amounts available for issuance under the 2015 Purchase Agreement had been utilized and the 2015 Purchase Agreement has expired pursuant to its terms. As such, no further shares will be sold under the 2015 Purchase Agreement.

2019 Purchase Agreement

On June 7, 2019, the Company entered into a $50,000,000 purchase agreement (the "2019 Purchase Agreement") with Lincoln Park, as amended on July 1, 2020 (the "Amendment Date"), pursuant to which the Company may sell and issue to Lincoln Park, and Lincoln Park is obligated to purchase, up to $50,000,000 in value of its shares of common stock from time to time from June 12, 2019, the date a prospectus supplement under which shares of common stock issuable under the 2019 Purchase Agreement was filed with the SEC, until July 1, 2022, which is the first day of the next month following the 36-month anniversary of June 12, 2019.

The Company may direct Lincoln Park, at its sole discretion, and subject to certain conditions, to purchase up to 200,000 shares of common stock on any business day (a "Regular Purchase"). The amount of a Regular Purchase may be increased under certain circumstances up to 250,000 shares, provided that Lincoln Park's committed obligation for Regular Purchases on any business day shall not exceed $2,000,000. In the event the Company purchases the full amount allowed for a Regular Purchase on any given business day, the Company may also direct Lincoln Park to purchase additional amounts as accelerated and additional accelerated purchases. The purchase price of shares of common stock related to the future funding will be based on the then prevailing market prices of such shares at the time of sales as described in the 2019 Purchase Agreement.

The Company's sale of shares of Common Stock to Lincoln Park subsequent to the Amendment Date is limited to 12,016,457 shares of Common Stock, representing 19.99% of the shares of the Common Stock outstanding on the Amendment Date unless (i) shareholder approval is obtained to issue more than such amount or (ii) the average price of all applicable sales of Common Stock to Lincoln Park under the 2019 Purchase Agreement after the Amendment Date equals or exceeds the lower of (A) the closing price of the Common Stock on the Nasdaq Capital Market immediately preceding the Amendment Date or (B) the average of the closing prices of the Common Stock on the Nasdaq Capital Market for the five Business Days immediately preceding the Amendment Date, and it also limits the Company's sale of shares to Lincoln Park to the extent it would cause Lincoln Park to beneficially own more than 4.99% of the Company's outstanding shares of Common Stock at any given time.

In consideration for entering into the 2019 Purchase Agreement, the Company issued to Lincoln Park 324,383 shares of common stock as a commitment fee and agreed to issue up to 162,191 shares pro rata, when and if, Lincoln Park purchases at the Company's discretion the $50,000,000 aggregate commitment.

During the year ended September 30, 2020, the Company issued to Lincoln Park an aggregate of 7,633,527 (2019 -1,839,415) shares of common stock under the 2019 Purchase Agreement, including 7,564,584 (2019: 1,500,000) shares of common stock for an aggregate purchase price of $21,254,298 (2019: $4,634,505) and 68,943 (2019: 339,415) commitment shares. At September 30, 2020, an amount of $24,111,197 (2019: $45,365,495) remained available under the 2019 Purchase Agreement.

Sales Agreement

The Company entered into a Controlled Equity Offering Sales Agreement on July 6, 2018, which was amended and restated on May 1, 2020 (the "Sales Agreement") with Cantor Fitzgerald & Co. and SVB Leerink LLC (together the "Sales Agents"), pursuant to which the Company may offer and sell shares of common stock, for aggregate gross sale proceeds of up to $50,000,000 from time to time through the Sales Agents (the "Offering").

Upon delivery of a placement notice based on the Company's instructions and subject to the terms and conditions of the Sales Agreement, the Sales Agents may sell the Shares by methods deemed to be an "at the market offering" offering, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, or by any other method permitted by law, including negotiated transactions, subject to the prior written consent of the Company. The Company is not obligated to make any sales of Shares under the Sales Agreement. The Company or Sales Agents may suspend or terminate the offering of Shares upon notice to the other party, subject to certain conditions. The Sales Agents will act as agent on a commercially reasonable efforts basis consistent with their normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of Nasdaq.

Note 4 Equity Offering Agreements (continued)

The Company has agreed to pay the Sales Agents commissions for their services of up to 3.0% of the gross proceeds from the sale of the Shares pursuant to the Sales Agreement. The Company also agreed to provide the Sales Agents with customary indemnification and contribution rights. During the year ended September 30, 2020, 1,760,429 shares were sold pursuant to the Offering for gross proceeds of $7,499,900 (net proceeds of $7,096,136 after deducting offering expenses). At September 30, 2020, an amount of $42,500,100 remained available under the Sales Agreement.

Note 5 Commitments

a) Lease

During the year ended September 30, 2020 the Company incurred office lease expense of $233,423 (2019: $190,416).

b) Litigation

The Company is subject to claims and legal proceedings that arise in the ordinary course of business. Such matters are inherently uncertain, and there can be no guarantee that the outcome of any such matter will be decided favorably to the Company or that the resolution of any such matter will not have a material adverse effect upon the Company's consolidated financial statements. The Company does not believe that any of such pending claims and legal proceedings will have a material adverse effect on its consolidated financial statements.

c) Share Purchase Warrants

The following table summarizes the warrant activity during the years ended September 30, 2020 and 2019:

	Number of Shares	Weighted Average Exercise Exercise Price ($)
Balance , September 30 , 2018.	678,379	2.87
Exercised	(8,750)	1.13
Expired.	(319,629)	1.46
Balance , September 30 , 2019.	350,000	4.19
Granted.	150,000	3.17
Balance, September 30, 2020.	500,000	3.88

During the year ended September 30, 2019, the Company issued 4,938 shares in connection with the exercise of 8,750 warrants on a cashless basis.

At September 30, 2020 the Company had share purchase warrants outstanding as follows:

Number	Exercise Price	Expiry Date
350,000	$ 4.19	June 30, 2021
150,000	$ 3.17	May 6, 2024
500,000		

d) Stock–based Compensation Plan

2015 Stock Option Plan

On September 18, 2015, the Company's board of directors approved a 2015 Omnibus Incentive Plan (the "2015 Plan"), which provided for the grant of stock options and restricted stock awards to directors, officers, employees and consultants of the Company.

The maximum number of our common shares reserved for issue under the plan was 6,050,553 shares, subject to adjustment in the event of a change of the Company's capitalization. At September 30, 2020, 146,371 (2019: 146,371) options remain available for issue under the 2015 Plan.

2019 Stock Option Plan

Note 5 Commitments (continued)

On January 15, 2019, the Board approved the 2019 Omnibus Incentive Plan (the "2019 Plan"), which provides for the grant of stock options and restricted stock awards to directors, officers, employees, consultants and advisors of the Company. Under the terms of the 2019 Plan, 6,000,000 additional shares of Common Stock are available for issuance under the 2019 Plan, in addition to the shares available under the 2015 Plan. Any awards outstanding under the 2015 Plan or the Company's 2007 Stock Option Plan (the "2007 Plan") will remain subject to and be paid under the 2015 Plan or the 2007 Plan, respectively, and any shares subject to outstanding awards under the 2015 Plan or the 2007 Plan that subsequently cease to be subject to such awards (other than by reason of settlement of the awards in shares) will automatically become available for issuance under the 2019 Plan.

The 2019 Plan provides that it may be administered by the Board, or the Board may delegate such responsibility to a committee. The exercise price will be determined by the board of directors at the time of grant shall be at least equal to the fair market value on such date. If the grantee is a 10% stockholder on the grant date, then the exercise price shall not be less than 110% of fair market value of the Company's shares of common stock on the grant date. Stock options may be granted under the 2019 Plan for an exercise period of up to ten years from the date of grant of the option or such lesser periods as may be determined by the board, subject to earlier termination in accordance with the terms of the 2019 Plan. At September 30, 2020, 3,161,665 (2019: 4,788,333) options remain available for issue under the 2019 Plan.

A summary of the status of Company's outstanding stock purchase options is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value ($)	Aggregate intrinsic value ($)
Outstanding, September 30, 2018	6,506,917	3.83		2,353,088
Granted	2,265,399	2.79	2.27	
Forfeited	(309,383)	3.25		
Outstanding, September 30, 2019	8,462,933	3.58		4,115,032
Granted	1,695,000	2.96	2.27	
Forfeited	(68,332)	3.01		
Exercised	(13,335)	3.15		
Outstanding, September 30, 2020	10,076,266	3.48		14,982,581
Exercisable, September 30, 2020	7,412,100	3.66		10,763,906

During the year ended September 30, 2020, the Company issued 721 shares in connection with the exercise of 13,335 options on a cashless basis.

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the quoted market price of the Company's stock for the options that were in-the-money on the applicable date.

The Company recognized stock-based compensation expense of $4,876,906 during the year ended September 30, 2020 (2019: $6,430,873) in connection with the issuance and vesting of stock options and warrants in exchange for services. These amounts have been included in general and administrative expenses and research and development expenses on the Company's consolidated statements of operations as follows:

	2020	2019
General and administrative	$ 2,210,789	$ 3,203,165
Research and development	2,666,117	3,227,708
Total share based compensation	$ 4,876,906	$ 6,430,873

An amount of approximately $4,040,812 in stock-based compensation is expected to be recorded over the remaining term of such options and warrants through 2023.

Note 5 Commitments (continued)

The fair value of each option and warrant award is estimated on the date of grant using the Black Scholes option pricing model based on the following weighted average assumptions:

	2020	2019
Risk-free interest rate	1.57%	2.50%
Expected life of option (years)	5.53	6.05
Annualized volatility	95.99%	104.45%
Dividend rate	0.00%	0.00%

The fair value of stock compensation charges recognized during the years ended September 30, 2020 and 2019 was determined with reference to the quoted market price of the Company's shares on the grant date.

Note 6 Income Taxes

The Company's U.S. and foreign loss before income taxes are set forth below:

	2020	2019
United States	$ (18,096,148)	$ (18,031,016)
Foreign	(8,161,658)	(8,181,782)
Total	$ (26,257,806)	$ (26,212,798)

The components of net deferred income tax assets as of September 30, 2020 and 2019 are as follows:

	2020	2019
Net operating loss carryforwards	$ 23,397,000	$ 18,704,000
Research and development tax credit carry forwards	2,069,000	1,162,000
Stock-based compensation	8,283,000	6,570,000
Unpaid charges	83,000	69,000
Intangible asset costs	132,000	30,000
Foreign exchange and other	27,000	15,000
Valuation allowance deferred tax assets	(33,991,000)	(26,550,000)
Net deferred tax assets	$ —	$ —

A reconciliation of income tax expense at the statutory federal income tax rate and income taxes as reflected in the consolidated financial statements for the years ended September 30, 2020 and 2019 is as follows:

	2020	2019
Income tax benefit at statutory federal rate	$ (5,519,000)	$ (5,505,000)
Foreign income taxed at other rates	(723,000)	(825,000)
Other permanent differences	35,000	140,000
Research and development credit benefit	1,267,000	914,000
State and local taxes	(2,911,000)	(1,487,000)
Adjustment and true up to prior year tax provision	373,000	194,000
Effect of change in statutory rates	36,000	—
State minimum and excise taxes	22,664	82,181
Change in valuation allowances	7,442,000	6,569,000
Income tax expense	$ 22,664	$ 82,181

As of September 30, 2020, the Company had U.S. federal net operating loss carryforwards of approximately $76.8 million (2019: $60.8 million) which will begin to expire in 2027 and state and local net operating loss carryforwards of approximately $103.1 million (2019: $64.0 million) which will begin to expire in 2036, The Company had approximately $4.3 million (Approximately AUD$ 6.0 million) (2019: $3.5 million) of net operating loss carryforwards in Australia, which have an indefinite life, available to offset future taxable income in those jurisdictions.

Note 2 Income Taxes (continued)

The Company evaluates its valuation allowance requirements based on available evidence. When circumstances change, and this causes a change in management's judgment about the recoverability of deferred tax assets, the impact of the change on the valuation allowance is reflected in current income. Because management of the Company does not currently believe that it is more likely than not that the Company will receive the benefit of these assets, a valuation allowance has been established at September 30, 2020 and 2019.

Uncertain Tax Positions

The Company files income tax returns in the U.S. federal jurisdiction and various state and local and foreign jurisdictions. The Company's tax returns are subject to tax examinations by U.S. federal and state tax authorities, or examinations by foreign tax authorities until the respective statutes of limitation expire. The Company is subject to tax examinations by tax authorities for all taxation years commencing on or after 2013.

Under the provisions of the Internal Revenue Code, the net operating loss ("NOL") carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL and tax credit carryforwards may become subject to an annual limitation in the event of an over 50% cumulative change in the ownership interest of significant stockholders over a three-year period, as defined under Sections 382 and 383 of the Internal Revenue Code, as well as similar state tax provisions. This could limit the amount of NOLs that the Company could be entitled to utilize annually to offset future taxable income or tax liabilities. The amount of the annual limitation, if any, would be determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may affect the limitation in future years. The Company completed a Section 382 analysis through the fiscal year ended September 30, 2020 and currently does not believe Section 382 will apply to limit the utilization of available NOLs.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL MATTERS

Not Applicable

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that material information required to be disclosed in our periodic reports filed under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, our chief executive officer and our principal financial officer, to allow timely decisions regarding required disclosure.

We carried out an evaluation, under the supervision and with the participation of our management, including our principal executive and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13(a)-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of September 30, 2020.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Principal Executive Officer and Principal Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in the framework in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO").

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Based on this evaluation, our management concluded that our internal controls over financial reporting were effective as of September 30, 2020.

Changes in Internal Control over Financial Reporting

During the quarter ended September 30, 2020, there were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a 15(d) or 15d 15(d) of the Exchange Act that materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

ITEM 9B OTHER INFORMATION

None.

PART III

ITEM 10 DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors and Executive Officers

Our directors are to be elected at our annual meeting and each director elected is to hold office until his or her successor is elected and qualified. Our board of directors may remove our officers at any time.

Our directors and executive officers, their age, positions held, and duration of such, are as follows:

Name	Position	Age	Date first appointed
Christopher Missling, PhD	Director, President, Chief Executive Officer, Secretary	55	July 5, 2013
Athanasios Skarpelos	Director	54	January 9, 2013
Claus van der Velden, PhD	Director	48	March 2, 2018
Elliot Favus, MD	Director	46	May 7, 2014
Steffen Thomas, PhD	Director	54	June 15, 2015
Peter Donhauser, D.O.	Director	55	February 8, 2017
Sandra Boenisch, CPA, CGA	Principal Financial Officer, Treasurer	39	October 1, 2015

Business Experience

The following is a brief account of the education and business experience of directors and executive officers during at least the past five years, indicating their principal occupation during the period, and the name and principal business of the organization by which they were employed.

Christopher Missling, PhD. Christopher Missling has over twenty years of healthcare industry experience in big pharmaceutical, biotech industry and investment banking. Most recently, from March 2007 until his appointment by our Company, Dr. Missling served as the head of healthcare investment banking at Brimberg & Co. in New York, New York. Also, Dr. Missling served as the Chief Financial Officer of Curis, Inc. (NASDAQ:CRIS) and ImmunoGen, Inc. (NASDAQ:IMGN). Dr. Missling earned his MS and PhD from the University of Munich and an MBA from Northwestern University Kellogg School of Management and WHU Otto Beisheim School of Management.

Athanasios Skarpelos. Athanasios (Tom) Skarpelos is a self-employed investor with over 20 years of experience working with private and public companies. For more than 12 years, he has been focused on biotechnology companies involved in drug discovery and drug development projects. His experience has led to relationships with researchers at academic institutes in Europe and North America. Mr. Skarpelos is a founder of Anavex.

Claus van der Velden, PhD. Claus van der Velden, PhD, brings significant expertise in management, accounting, internal controls and risk management. Since July of 2011, he has served as corporate head of Management Accounting, Internal Audit and Risk Management at Stroeer SE & Co KGaA, a publicly listed German digital media company. Previously, Dr. van der Velden served as the Director of Corporate Business Controlling for the Nutrition & Health business unit at Cognis, a worldwide supplier of global nutritional ingredients and specialty chemicals. In this position, he was also a compliance representative and a member of the global leadership team. After the acquisition of Cognis by BASF, he was responsible for the management accounting processes of the BASF Nutrition& Health division, developing and producing mostly natural-source ingredients for the food and healthcare industries. Dr. van der Velden started his career as a strategy consultant at an international marketing and strategy consultancy firm. He studied in Kiel and Stockholm and received a degree in economics from the University of Kiel and later obtained his doctorate in business management from the WHU-Otto Beisheim School of Management where he also previously taught economics.

Elliot Favus, MD. Elliot Favus is Chief Executive Officer of Favus Institutional Research, a healthcare research firm serving institutional investors. He has been a healthcare equity research analyst on Wall Street since 2006, starting at Lazard Capital Markets and subsequently at Och-Ziff Capital Management Group. Prior to working on Wall Street, Dr. Favus was an Instructor in medicine at Mount Sinai School of Medicine in New York. He attended the University of Michigan (BA, 1996), the University of Chicago Pritzker School of Medicine (MD, 2001) and the NYU-Bellevue

Hospital Internal Medicine Residency Program (2004). He is board-certified in Internal Medicine (2004) and has 10 years of basic science laboratory experience working on human genetics projects at Harvard Medical School, the University of Chicago and the University of Pittsburgh.

Steffen Thomas, PhD. Steffen Thomas, has over 15 years of experience as a European patent attorney and is currently practicing at Epping Hermann Fischer, a major intellectual property law firm in Europe. Previously, he worked for Japan-based Takeda Pharmaceutical Company, the largest pharmaceutical company in Asia and a top firm worldwide, as an in-house patent attorney. Prior to that, he worked for Nycomed Pharma, acquired by Takeda in 2011 for approximately USD $10 billion. Dr. Thomas' legal practice covers drafting of patent applications, prosecuting patent applications before national and international patent offices, defending and challenging patents in opposition, appeal, and nullity proceedings, enforcing patents before the infringement courts, and preparing opinions on patentability and infringement in the technical field of chemistry. Dr. Thomas has particular expertise in small molecule pharmaceuticals. He holds MS and PhD degrees in Chemistry from the University of Munich.

Peter Donhauser, D.O. Peter Donhauser, had more than 20 years of expertise in clinical research prior to practicing osteopathic medicine with an integrated medical approach in private practice beginning in 2000. He worked at the University Hospital of Munich in the fields of geriatrics and neuromusculoskeletal diseases. During this time, he was a clinical trial investigator in multiple Phase 3 studies, including studies sponsored by Merck Sharp & Dohme, Merck, Boehringer Mannheim, Roche, Servier and Sanofi. He received his human medicine degree at the University of Munich and Doctor of Osteopathic Medicine (D.O.) from the German-American Academy for Osteopathy, or DAAO, a member of the European Register for Osteopathic Physicians, or EROP, at the Philadelphia College of Osteopathic Medicine.

Sandra Boenisch, CPA, CGA. Ms. Boenisch is a Chartered Professional Accountant (CPA, CGA) with over 15 years of accounting, audit, and financial reporting experience in a variety of industries, both in the United States and Canada. Ms. Boenisch was an independent consultant, providing financial reporting services to a range of public companies in the United States and Canada since January 2012. From 2008 until 2012, Ms. Boenisch was employed at BDO Canada LLP (Vancouver, BC) where she was hired as a Senior Accountant and was later promoted to Manager, Audit Assurance. Ms. Boenisch specialized in managing assurance engagements for public companies in the United States and Canada. Prior to that, Ms. Boenisch worked for another public accounting firm from 2001 to 2008. As an independent consultant, Ms. Boenisch has acquired considerable experience in finance, governance, and regulatory compliance. She holds a BComm from Laurentian University.

Family Relationships

There are no family relationships between any director or executive officer.

Involvement in Certain Legal Proceedings

There are no material proceedings to which any director or executive officer or any associate of any such director or officer is a party adverse to our Company or has a material interest adverse to our Company.

Compliance with Section 16(a) of the Securities Exchange Act of 1934

Section 16(a) of the Securities Exchange Act of 1934 requires our executive officers and directors and persons who own more than 10% of our common stock to file with the Securities and Exchange Commission initial statements of beneficial ownership, reports of changes in ownership and annual reports concerning their ownership of our common stock and other equity securities, on Forms 3, 4 and 5 respectively. Executive officers, directors and greater than 10% shareholders are required by the Securities and Exchange Commission regulations to furnish us with copies of all Section 16(a) reports that they file.

Based solely on the copies of such reports and amendments thereto received by us, or written representations that no filings were required, we believe that all Section 16(a) filing requirements applicable to our executive officers and directors and 10% stockholders were met for the year ended September 30, 2020.

Code of Ethics

We have adopted a code of ethics that applies to our directors, principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and to all employees. We have posted our policy on our website at www.anavex.com.

Audit Committee and Audit Committee Financial Experts

The members of the Audit Committee are Claus van der Velden (Chairman), Athanasios Skarpelos and Steffen Thomas. Our board of directors has determined that Claus van der Velden is an "audit committee financial expert" as defined by applicable SEC and Nasdaq rules.

The Audit Committee oversees and reports to our board of directors on various auditing and accounting-related matters, including, among other things, the maintenance of the integrity of our financial statements, reporting process and internal controls; the selection, evaluation, compensation and retention of our independent registered public accounting firm; legal and regulatory compliance, including our disclosure controls and procedures; and oversight over our risk management policies and procedures.

The Audit Committee operates under a charter that was adopted by our board of directors. The Audit Committee met five times during fiscal 2020.

Nominating and Corporate Governance Committee

The members of our Nominating and Corporate Governance Committee are Claus van der Velden (Chairman), Steffen Thomas and Peter Donhauser.

The Nominating and Corporate Governance Committee is appointed by the Board to oversee and evaluate the Board's performance and the company's compliance with corporate governance regulations, guidelines and principles, to identify individuals qualified to become Board members, to recommend to the Board proposed nominees for Board membership, and to recommend to the Board directors to serve on each standing committee. The Nominating and Corporate Governance Committee did not meet but did act by written consent during fiscal 2020.

Compensation Committee

The members of our Compensation Committee are Claus van der Velden (Chairman), Steffen Thomas and Peter Donhauser.

The Compensation Committee assists our board of directors in discharging its responsibilities relating to compensation of our directors and executive officers. Its responsibilities include, among other things, reviewing, approving and recommending compensation programs and arrangements applicable to our officers; determining the objectives of our executive officer compensation programs; overseeing the evaluation of our senior executives; administering our incentive compensation plans and equity-based plans, including reviewing and granting equity awards to our executive officers; and reviewing and approving director compensation and benefits. The Compensation Committee can delegate to other members of our board of directors, or an officer or officers of the Company, the authority to review and grant stock-based compensation for employees who are not executive officers.

The Compensation Committee has the responsibilities and authority designated by Nasdaq rules. Specifically, the Compensation Committee has the sole discretion to select and receive advice from a compensation consultant, legal counsel or other adviser and is directly responsible for oversight of their work. The Compensation Committee must also determine reasonable compensation to be paid to such advisors by us.

Prior to the formation of our Compensation Committee, our board of directors performed the functions that would have been handled by the Compensation Committee.

The Compensation Committee operates under a charter that was adopted by our board of directors. The Compensation Committee met one time during fiscal 2020 and also acted by written consent as required.

ITEM 11. EXECUTIVE COMPENSATION

The Company's compensation objectives are to offer our executive officers' compensation and benefits that are competitive and meet our goals of attracting, retaining and motivating highly skilled, talented management, which is necessary for the Company to achieve its financial and strategic objectives and create long-term value for our stockholders.

A significant portion of the Company's executive compensation opportunity is related to factors that directly and indirectly influence shareholder value, including long-term stock performance and operational performance. We believe the levels of compensation we provide should be competitive, reasonable and appropriate for our business needs and circumstances.

Our Executive Compensation Program and Philosophy

The intent of the Company's compensation program is to attract and retain talent, to create incentives for and to reward excellent performance. We seek to compensate our executives in a manner that is competitive, rewards performance that creates shareholder value, recognizes individual contributions, and encourages long-term value creation.

The Compensation Committee meets at least twice per year to review and evaluate executive compensation and each executive officer's performance. The Compensation Committee utilizes quantitative and qualitative factors, including the accomplishment of initiatives, attitude, and leadership and applies overall judgment to assess performance, taking into account the financial condition of the Company. Ultimately, the Compensation Committee seeks to evaluate, based on the achievement of financial and nonfinancial objectives, the variable compensation, including special awards, of executive officers of the Company and decide on the base salary and target discretionary bonus for such persons taking into account relevant benchmark data.

The Compensation Committee believes that a significant portion of each executive's compensation opportunity should be tied to variable compensation and value creation for shareholders. The Compensation Committee believes this mix provides an appropriate balance between the financial security required to attract and retain qualified individuals, and the Compensation Committee's goal of ensuring that executive compensation rewards performance that benefits shareholders over the long term.

Compensation Consultants

The Compensation Committee makes recommendations to the Board for all compensation for executives, including the structure and design of the compensation programs. The Compensation Committee is responsible for retaining and terminating compensation consultants and determining the terms and conditions of their engagement. During fiscal 2020, the Compensation Committee did not engage any compensation consultants.

Annual Discretionary Cash Bonuses

The Company has an annual discretionary cash bonus program. The Compensation Committee, or board of directors works with the Chief Executive Officer to evaluate the Company's financial performance and overall financial condition to determine if discretionary bonuses are to be paid.

Benefits

The Company's executives are entitled to participate in employee benefit plans, programs and arrangements implemented by the Company and generally available to all salaried employees, such as medical, dental and insurance programs. Executives are also allowed to participate in the Company's tax-qualified 401(k) Plan offered to all similarly situated full-time employees.

Summary Compensation

The particulars of compensation paid to our named executive officers for the last two completed fiscal years:

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Other Compen-sation ($)	Total ($)
Christopher Missling, PhD	2020	550,000	55,000	—	1,224,648	11,400	1,841,048
President, Chief Executive Officer, and Director	2019	512,500	50,000	—	2,806,339	11,200	3,380,039
Sandra Boenisch[(1)]	2020	117,041	22,313	—	155,864	—	295,218
Principal Financial Officer and Treasurer	2019	72,327	13,561	—	138,672	—	224,560

(1) Compensation to Ms. Boenisch denominated in Canadian Dollars has been translated to US dollars at an exchange rate of 0.7438 during the year ended September 30, 2020 (2019: 0.7534).

Employment Agreements

Christopher Missling

We and Dr. Missling entered into an employment agreement dated July 5, 2013, as amended and extended (the "CEO Employment Agreement"), whereby we currently pay to Dr. Missling an annual base salary of $550,000. In addition, Dr. Missling is eligible to earn an annual cash bonus for each whole or partial calendar year of up to twenty percent of his base salary, and to participate in our employee benefit plans. We have agreed to indemnify Dr. Missling in connection with his provision of services to us.

Sandra Boenisch

We and Ms. Boenisch entered into an amended and restated employment agreement dated October 4, 2017, as amended and extended, whereby we currently pay Ms. Boenisch an annual base salary of $200,000 Canadian dollars, effective March 1, 2020. Ms. Boenisch is eligible for discretionary salary increases.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth for each named executive officer and director certain information concerning the outstanding equity awards as of September 30, 2020.

	Option Awards					Stock Awards			
Name	Number of Securities Underlying Exercisable Options (#)	Number of Securities Underlying Unexercisable Options (#)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares of Units of Stock that have not Vested (#)	Market Value of Shares or Units of Stock that have not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights that have not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights that have not Vested ($)
Christopher Missling	500,000	—	—	1.60	July 5, 2023	—	—	—	—
	125,000	—	—	1.32	May 8, 2024				
	500,000	—	—	0.92	April 2, 2025				
	187,500	—	—	5.04	Sept 18, 2025				
	379,625	—	—	6.26	July 5, 2026				
	861,429	—	—	7.06	July 18, 2026				
	500,000	—	—	3.28	Sept 22, 2026				
	450,000	—	—	5.92	May 12, 2027				
	366,666	33,334	—	3.30	Dec 13, 2027				
	450,000	—	—	2.30	May 15, 2028				
	409,500	—	—	2.58	Oct. 1, 2028				
	250,000	500,000	—	3.15	May 3, 2029				
	—	550,000	—	2.96	January 6, 2030				
Sandra Boenisch	25,000	—	—	5.68	Oct 2, 2025	—	—	—	—
	106,696	—	—	3.28	Sept 22, 2026				
	35,000	—	—	5.92	May 12, 2027				
	27,500	2,500	—	3.30	Dec 13, 2027				
	30,000	—	—	2.30	May 15, 2028				
	27,300	—	—	2.58	Oct. 1, 2028				
	—	35,000	—	2.93	June 4, 2029				
	—	70,000	—	2.96	January 6, 2030				

Stock Option Plans

For a description of our Equity Compensation Plans, please see Item 5 to this annual report on Form 10-K.

Compensation of Directors

The table below shows the compensation of our directors who were not our named executive officers for the fiscal year ended September 30, 2020:

Name	**Fees Earned or Paid in Cash ($)**	**Stock Awards ($)**	**Option Awards ($)[1]**	**Non-Equity Incentive Plan Compensation ($)**	**Nonqualified Deferred Compensation Earnings ($)**	**All Other Compensation ($)**	**Total ($)**
Athanasios Skarpelos	—	—	111,320	—	—	—	111,320
Claus van der Velden	16,000	—	111,320	—	—	—	127,320
Elliot Favus	—	—	111,320	—	—	—	111,320
Steffen Thomas	—	—	111,320	—	—	—	111,320
Peter Donhauser	—	—	111,320	—	—	—	111,320

(1) At September 30, 2020, the aggregate number of outstanding vested and unvested stock option awards held by each director was: Mr. Skarpelos options to purchase 245,500 shares, Mr. Van der Velden options to purchase 145,500 shares, Mr. Favus options to purchase 290,500 shares, Mr. Thomas options to purchase 245,500 shares and Mr. Donhauser options to purchase 145,500 shares.

We currently compensate Claus van der Velden $4,000 per quarter for performing the functions of Chairman of our Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee.

In addition, directors are entitled to reimbursement for reasonable travel and other out-of-pocket expenses incurred in connection with attendance at meetings of our board of directors. Our board of directors may award further special remuneration to any director undertaking any special services on our behalf other than services ordinarily required of a director.

Retirement or Similar Benefit Plans

There are no arrangements or plans in which we provide retirement or similar benefits for our directors or executive officers.

Resignation, Retirement, Other Termination, or Change in Control Arrangements

Our Employment Agreement with Dr. Missling contains provisions regarding our obligations upon his termination and upon a change of control. In the event of a change of control, as such term is defined in the employment agreement, all previously granted but unvested stock options held by Dr. Missling shall vest. Depending on the nature of the termination of Dr. Missling's services, certain of his salary, bonus and granted securities shall vest in the amounts at such time as set forth in the Employment Agreement. A copy of Dr. Missling's Second Amendment to Employment Agreement is set forth in its entirety as an exhibit hereto.

Our employment agreement with Sandra Boenisch contains provisions regarding our obligations to Ms. Boenisch upon a change of control. In the event of a change of control, as such term is defined in the employment agreement, all of the remaining unvested option shares granted to Ms. Boenisch will immediately vest with no restrictions on purchase or sales. A copy of Ms. Boenisch's employment agreement is set forth in its entirety as an exhibit hereto.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The following table sets forth, as of December 28, 2020, certain information with respect to the beneficial ownership of our common stock by each stockholder known by us to be the beneficial owner of more than 5% of our common stock and by each of our current directors and our named executive officers and by our current directors and executive officers as a group. We have determined the number and percentage of shares beneficially owned by such person in accordance with Rule 13d-3 under the Securities Exchange Act of 1934. This information does not necessarily indicate beneficial ownership for any other purpose.

Title of class	Name and address of beneficial owner	Amount and nature of beneficial ownership	Percent of class[1]
Common Stock	Christopher Missling (CEO/Director)	6,031,264[2]	8.4%
Common Stock	Athanasios Skarpelos (Director)	1,551,958[3]	2.3%
Common Stock	Claus van der Velden (Director)	128,834[4]	*
Common Stock	Elliot Favus (Director)	290,500[5]	*
Common Stock	Steffen Thomas (Director)	245,500[6]	*
Common Stock	Peter Donhauser (Director)	145,500[7]	*
Common Stock	Sandra Boenisch (Principal Financial Officer)	276,959[8]	*
Common Stock	**Directors & Executive Officers as a group (7 persons)**	8,670,515	11.8%
Common Stock	BlackRock, Inc.	3,480,213	5.2%

*Less than 1%

(1) Percentage of ownership is based on 66,962,957 of our common stock issued and outstanding as of December 28, 2020. Except as otherwise indicated, we believe that the beneficial owners of the common stock listed above, based on information furnished by such owners, have sole investment and voting power with respect to such shares, subject to community property laws where applicable. Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and generally includes voting or investment power with respect to securities. Shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days, are deemed outstanding for purposes of computing the percentage ownership of the person holding such option or warrants but are not deemed outstanding for purposes of computing the percentage ownership of any other person.

(2) Includes options to purchase 500,000 shares of our common stock at $1.60 per share, options to purchase 125,000 shares of our common stock at $1.32 per share, options to purchase 500,000 shares of our common stock at $0.92 per share, options to purchase 187,500 shares of our common stock at $5.04 per share, options to purchase 379,625 shares of our common stock at $6.26 per share, options to purchase 861,429 shares of our common stock at $7.06 per share, options to purchase 500,000 shares of our common stock at $3.28 per share, and options to purchase 450,000 shares of our common stock at $5.92 per share, options to purchase 400,000 shares of our common stock at $3.30 per share, options to purchase 450,000 shares of our common stock at $2.30 per share, options to purchase 409,500 shares of our common stock at $2.58 per share and options to purchase 250,000 shares of our common stock at $3.15 per share that are vested or are vesting within 60 days. Excludes options to purchase 500,000 shares of our common stock at $3.15 per share and options to purchase 550,000 shares of our common stock at $2.96 per share that do not vest within 60 days.

(3) Includes options to purchase 50,000 shares of our common stock at $0.92 per share and options to purchase 100,000 shares of our common stock at $3.28 per share, options to purchase 45,500 shares of our common stock at $2.58 per share and options to purchase 50,000 shares of our common stock at $2.96 per share that have vested or are vesting within 60 days.

(4) Includes options to purchase 33,334 shares of our common stock at $2.60 per share, options to purchase 45,500 shares of our common stock at $2.58 per share and options to purchase 50,000 shares of our common stock at $2.96 per share that have vested or are vesting within 60 days. Excludes options to purchase 16,666 shares of our common stock at $2.60 per share that are not vesting within 60 days.

(5) Includes options to purchase 37,500 shares of our common stock at $1.20 per share, options to purchase 50,000 shares of our common stock at $0.92 per share, options to purchase 1,500 shares of our common stock at $5.64 per share, options to purchase 1,500 shares of our common stock at 5.57 per share, options to purchase 1,500 shares of our common stock at $4.90 per share, options to purchase 1,500 shares of our common stock at $5.66 per share, options to purchase 1,500 shares of our common stock at $6.11 per share, options to purchase 100,000 shares of our common stock at $3.28 per share, options to purchase 45,500 shares of our common stock at $2.58 per share and options to purchase 50,000 shares of our common stock at $2.96 per share that have vested or are vesting within 60 days.

(6) Includes options to purchase 50,000 shares of our common stock at $1.76 per share and options to purchase 100,000 shares of our common stock at $3.28 per share, options to purchase 45,500 shares of our common stock at $2.58 per share, and options to purchase 50,000 shares of our common stock at $2.96 per share that have vested or are vesting within 60 days.

(7) Includes options to purchase 50,000 shares of our common stock at $5.39 per share, options to purchase 45,500 shares of our common stock at $2.58 per share and options to purchase 50,000 shares of our common stock at $2.96 per share that have vested or are vesting within 60 days.

(8) Includes options to purchase 25,000 shares of our common stock at $5.68 per share, options to purchase 106,696 shares of our common stock at $3.28 per share, options to purchase 35,000 shares of our common stock at $5.92 per share, options to purchase 30,000 shares of our common stock at $3.30 per share, and options to purchase 30,000 shares of our common stock at $2.30 per share, and options to purchase 27,300 shares of our common stock at $2.58 per share that have vested or are vesting within 60 days. Excludes options to purchase 35,000 shares of common stock at $2.93 per share and options to purchase 70,000 shares of our common stock at $2.96 per share that do not vest within 60 days.

Change in Control

We are unaware of any contract or other arrangement the operation of which may at a subsequent date result in a change of control of our Company.

Securities Authorized for Issuance under Equity Compensation Plans or Individual Compensation Arrangements

The following table summarizes certain information regarding our equity compensation plan or individual compensation arrangements at September 30, 2020:

Equity Compensation Plan Information			
Plan Category	**Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)**	**Weighted-average exercise price of outstanding options, warrants and rights (b)**	**Number of securities remaining available for future issuances under equity compensation plans (excluding securities reflected in column (a)) (c)**
Equity compensation plans approved by security holders . . .	12,050,553	3.82	3,308,036
Equity compensation plans not approved by security holders . . .	—	—	—
Total	**12,050,553**	**3.82**	3,308,036

Stock Option Plan

2019 Stock Option Plan

On January 15, 2019, the Board approved the 2019 Omnibus Incentive Plan (the "2019 Plan"), which provides for the grant of stock options and restricted stock awards to directors, officers, employees, consultants and advisors of the Company. The 2019 Plan was approved by our stockholders on April 5, 2019.

Under the terms of the 2019 Plan, 6,000,000 shares of Common Stock are available for issuance, in addition to the shares available under the 2015 Plan. Any awards outstanding under the Company's 2015 Omnibus Incentive Plan (the "2015 Plan") or the Company's 2007 Stock Option Plan (the "2007 Plan") will remain subject to and be paid under the 2015 Plan or the 2007 Plan, respectively, and any shares subject to outstanding awards under the 2015 Plan or the 2007 Plan that subsequently cease to be subject to such awards (other than by reason of settlement of the awards in shares) will automatically become available for issuance under the 2019 Plan.

The 2019 Plan provides that it may be administered by the Board, or the Board may delegate such responsibility to a committee. The exercise price will be determined by the board of directors at the time of grant shall be at least equal to the fair market value on such date. If the grantee is a 10% stockholder on the grant date, then the exercise price shall not be less than 110% of fair market value of the Company's shares of common stock on the grant date. Stock options may be granted under the 2019 Plan for an exercise period of up to ten years from the date of grant of the option or such lesser periods as may be determined by the board, subject to earlier termination in accordance with the terms of the 2019 Plan.

The purpose of the 2019 Plan is to retain the services of valued key employees and consultants of our Company and such other persons, and to encourage such persons to acquire a greater proprietary interest in our Company, thereby strengthening their incentive to achieve the objectives of the shareholders of our Company. The purpose is also to serve as an aid and inducement in the hiring of new employees and to provide an equity incentive to consultants.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Transactions with related persons

There have been no transactions, since October 1, 2018, or currently proposed transactions, in which we were or are to be a participant and the amount involved exceeds the lesser of $120,000 or one percent of the average of the smaller reporting company's total assets at year end for the last two completed fiscal years, and in which any of the following persons had or will have a direct or indirect material interest.

i. any director or executive officer of our Company;

ii. any beneficial owner of shares carrying more than 5% of the voting rights attached to our outstanding shares of common stock; and

iii. any member of the immediate family (including spouse, parents, children, siblings and in-laws) of any of the foregoing persons.

Compensation of Named Executive Officers and Directors

For information regarding compensation of named executive officers and directors, please see "Item 11. Executive Compensation."

Director Independence

Under the NASDAQ Stock Market Rules, the Board has a responsibility to make an affirmative determination that those members of its Board that serve as independent directors do not have any relationships with the Company and its businesses that would impair their independence. The Board has determined that that Christopher Missling, PhD is not independent as that term is defined by NASDAQ 5605(a)(2) because Mr. Missling serves as our President, Chief Executive Officer, and Secretary.

The Board has determined that that Claus van der Velden, Elliot Favus, Athanasios Skarpelos, Steffen Thomas and Peter Donhauser are independent as that term is defined by NASDAQ 5605(a)(2) and the applicable rules of the Securities and Exchange Commission.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Fees Paid to Our Independent Registered Public Accounting Firm

The following table sets forth the aggregate fees billed or expected to be billed to our Company for professional services rendered by our independent registered public accounting firm, for the fiscal years ended September 30, 2020 and 2019:

	2020	2019
Audit Fees	$ 305,751	$ 229,763
Audit Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total Fees	$ 305,751	$ 229,763

Audit Fees. Consist of fees billed for professional services rendered for the audits of our financial statements, reviews of our interim financial statements included in quarterly reports, services performed in connection with regular filings with the Securities and Exchange Commission for the fiscal years ended September 30, 2020 and 2019 in connection with statutory and regulatory filings or engagements.

Policy on Pre-Approval by Audit Committee of Services Performed by Independent Registered Public Accounting Firm

Our Audit Committee pre-approves all services provided by our independent registered public accounting firm. All of the above services and fees were reviewed and approved by our Audit Committee before the respective services were rendered.

Our Audit Committee has considered the nature and amount of fees billed or expected to be billed by BDO USA, LLP and believes that the provision of services for activities unrelated to the audit was compatible with maintaining BDO USA, LLP's independence.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Exhibit Number	Description
(3)	Articles of Incorporation and Bylaws
3.1	Articles of Incorporation (incorporated by reference to our Registration Statement on Form SB-2 filed on January 13, 2005)
3.2	Bylaws (incorporated by reference to our Current Report on Form 8-K filed on September 28, 2007)
3.3	Articles of Merger filed with the Secretary of State of Nevada on January 10, 2007 and which is effective January 25, 2007 (incorporated by reference to our Current Report on Form 8-K filed on January 25, 2007)
(10)	**Material Contracts**
10.1	2015 Omnibus Incentive Plan (incorporated by reference to our Annual Report on Form 10-K filed on December 29, 2015)
10.2	2019 Omnibus Incentive Plan (incorporated by reference to our Proxy Statement, dated February 11, 2019, as filed on February 11, 2019).
10.3	Purchase Agreement, dated as of June 7, 2019, by and between the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to our Current Report on Form 8-K filed on June 12, 2019)
10.4	Registration Rights Agreement, dated as of June 7, 2019, by and between the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to our Current Report on Form 8-K filed on June 12, 2019)
10.5	First Amendment to Purchase Agreement, dated as of July 1, 2020, by and between the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to our Current Report on Form 8-K filed on July 2, 2020)
10.6	First Amendment to Employment Agreement, dated as of July 5, 2016, by and between the Company and Christopher Missling, PhD (incorporated by reference to our Current Report on Form 8-K filed on July 7, 2016)
10.7	Amended and Restated First Amendment to Employment Agreement, dated as of July 18, 2016, by and between the Company and Christopher Missling, PhD (incorporated by reference to our Current Report on Form 8-K filed on July 22, 2016)
10.8	Second Amendment to Employment Agreement, dated as of May 3, 2019 by and between the Company and Christopher Missling, PhD (incorporated by reference to our Quarterly Report on Form 10-Q filed on May 9, 2019)
10.9	Amended and Restated Employment Agreement by and between the Company and with Sandra Boenisch (incorporated by reference to our Annual Report on Form 10-K filed on December 11, 2017)
10.10	Amendment No. 1 to Amended and Restated Employment Agreement between the Company and Sandra Boenisch, dated February 4, 2020 (incorporated by reference to our Quarterly Report on Form 10-Q filed on February 6, 2020)
10.11	Amended and Restated Sales Agreement, dated May 1, 2020, by and among Anavex Life Sciences Corp., Cantor Fitzgerald & Co. and SVB Leerink LLC (incorporated by reference to our Current Report on Form 8-K filed on May 1, 2020)
14	**Code of Ethics**
14.1	Code of Ethics Adopted on September 13, 2016 (incorporated by reference to our Annual Report on Form 10-K filed on December 14, 2016)
(21)	**Subsidiaries**
21.1*	Subsidiaries of the Registrant
(23)	**Consent**
23.1*	Consent of Independent Registered Public Accounting Firm
(31)	**Section 302 Certifications**
31.1*	Section 302 Certification of Christopher Missling, PhD.
31.2*	Section 302 Certification of Sandra Boenisch

Exhibit Number	Description
(32)	**Section 906 Certifications**
32.1*	Section 906 Certification of Christopher Missling, PhD and Sandra Boenisch
(99)	**Additional Exhibits**
99.1	Insider Trading Policy Adopted August 9, 2017 (incorporated by reference to our Annual Report on Form 10-K filed on December 11, 2017)
(101)	**XBRL**
101.INS*	XBRL INSTANCE DOCUMENT
101.SCH*	XBRL TAXONOMY EXTENSION SCHEMA
101.CAL*	XBRL TAXONOMY EXTENSION CALCULATION LINKBASE
101.DEF*	XBRL TAXONOMY EXTENSION DEFINITION LINKBASE
101.LAB*	XBRL TAXONOMY EXTENSION LABEL LINKBASE
101.PRE*	XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE

* Filed herewith.

ITEM 16. FORM 10-K SUMMARY

Not Applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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: December 28, 2020

ANAVEX LIFE SCIENCES CORP.

By: */s/ Christopher Missling, PhD*

Name: Christopher Missling, PhD

Title: Chief Executive Officer (Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signatures	Title(s)	Date
/s/ Christopher Missling, PhD		December 28, 2020
Christopher Missling, PhD	Chief Executive Officer (Principal Executive Officer)	
/s/ Sandra Boenisch		December 28, 2020
Sandra Boenisch, CPA, CGA	Principal Financial Officer and Treasurer (Principal Accounting Officer)	
/s/ Athanasios Skarpelos		December 28, 2020
Athanasios Skarpelos	Director	
/s/ Claus van der Velden, PhD		December 28, 2020
Claus van der Velden, PhD	Director	
/s/ Elliot Favus, MD		December 28, 2020
Elliot Favus, MD	Director	
/s/ Steffen Thomas, PhD		December 28, 2020
Steffen Thomas, PhD	Director	
/s/ Peter Donhauser, D.O.		December 28, 2020
Peter Donhauser, D.O.	Director	