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0001314052 avxl:FederalMember 2021-09-30 0001314052 2021-09-30 0001314052 2024-07-01 2024-09-30 iso4217:USD xbrli:shares iso4217:USD xbrli:shares xbrli:pure Â Â UNITED STATESSECURITIES AND EXCHANGE COMMISSIONWashington, D.C. 20549Â FORM 10-KÂ (Mark One)Â â˜’Â ANNUALREPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934For the fiscal year ended September 30, 2024Â â˜Â TRANSITION REPORT PURSUANT TO SECTION13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934For the transition period from _____ to_____Â Commission file number: 001-37606Â ANAVEX LIFE SCIENCES CORP.(Exact name of registrant as specified in its charter)Â Nevada Â 98-0608404 (State or other jurisdiction of incorporation or organization) Â (I.R.S. Employer Identification No.) Â Â Â 630 5th Avenue, 20th Floor, New York, NY USA Â 10111 (Address of principal executive offices) Â (Zip Code) Â Registrantâ€™s telephone number, including areacode 1-844-689-3939Â Securities registered under Section 12(b) of the Act:Â Common Stock, $0.001 par value AVXL NASDAQ Stock Market LLC Title of each class Trading Symbol Name of each exchange on which registered Â Securities registered pursuant to Section 12(g) ofthe Act:Â None(Title of class)Â Indicateby checkmark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.Â YesÂ â˜’NoÂ â˜Â Indicateby checkmark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.Â YesÂ â˜No â˜’Â Â Â Indicateby checkmark whether the registrant has (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities ExchangeAct 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.Â YesÂ â˜’NoÂ â˜Â Indicateby check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule405 of Regulation S-T (Â§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrantwas required to submit and post such files).Â YesÂ â˜’NoÂ â˜Â Indicateby checkmark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reportingcompany, or an emerging growth company. See the definitions of â€œlarge accelerated filer,â€ â€œaccelerated filerâ€,â€œsmaller reporting companyâ€ and â€œemerging growth companyâ€ in

Rule 12b-2 of the Exchange Act.Â Large accelerated filer â˜ Â Accelerated filer â˜ Non-accelerated filer â˜’ Â Smaller reporting company â˜’ Â Â Emerging growth company â˜ Â Ifan emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complyingwith any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange ActÂ â˜Â Indicateby check mark whether the registrant has filed a report on and attestation to its managementâ€™s assessment of the effectivenessof its internal controls over financial reporting under SectionÂ 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registeredpublic accounting firm that prepared or issued its audit report.Â YesÂ â˜NoÂ â˜’Â Ifsecurities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrantincluded in the filing reflect the correction of an error to previously issued financial statementsÂ â˜Â Indicateby check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensationreceived by any of the registrantâ€™s executive officers during the relevant recovery period pursuant to Â§240.10D-1(b).Â â˜Â Indicateby check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).Â YesÂ â˜NoÂ â˜’Â State the aggregate market value of the voting andnon-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the averagebid and asked price of such common equity, as of the last business day of the registrantâ€™s most recently completed second fiscalquarter: $412 million based on a price of $5.09 per share, being the closing price of the registrantâ€™s common stock on March 31,2024.Â Indicate the number of shares outstanding of eachof the registrantâ€™s classes of common stock, as of the latest practicable date: 84,815,517 issued and outstanding as of December23, 2024.Â DOCUMENTS INCORPORATED BY REFERENCEÂ None.Â ii Â Â TABLE OF CONTENTSÂ PART I 6 ITEM 1. BUSINESS 6 ITEM 1A. RISK FACTORS 32 ITEM 1B. UNRESOLVED STAFF COMMENTS 62 ITEM 1C. CYBERSECURITY 62 ITEM 2. PROPERTIES 63 ITEM 3. LEGAL PROCEEDINGS 63 ITEM 4. MINE SAFETY DISCLOSURES 64 PART II 64 ITEM 5. MARKET FOR REGISTRANTâ€™S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES 64 ITEM 7 MANAGEMENTâ€™S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION 64 ITEM 7A QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK 70 ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA F-1 ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL MATTERS 71 ITEM 9A. CONTROLS AND PROCEDURES 71 ITEM 9B OTHER INFORMATION 71 ITEM 9C DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS 71 PART III 72 ITEM 10 DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE 72 ITEM 11. EXECUTIVE COMPENSATION 77 ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS. 83 ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE 86 ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES 87 PART IV 88 ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES 88 ITEM 16. FORM 10-K SUMMARY 89Â iii Â Â Forward Looking Statements.Â This Annual Report on Form 10-K includes forward-lookingstatements. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statementsregarding our anticipated future clinical and regulatory milestone events, future financial position, business strategy and plans andobjectives of management for future operations, are forward-looking statements. The words â€œbelieve,â€ â€œmay,â€ â€œestimate,â€â€œcontinue,â€ â€œanticipate,â€ â€œintend,â€ â€œexpect,â€ â€œshould,â€ â€œforecast,â€â€œpotential,â€ â€œpredict,â€ â€œcould,â€ â€œwouldâ€, â€œwillâ€, â€œsuggest,â€ â€œplanâ€and similar expressions, as they relate to us, are intended to identify forward-looking statements. Such forward-looking statements include,without limitation, statements regarding:Â Â·volatility in our stock price and in the marketsin general;Â Â·our ability to successfully conduct preclinicalstudies and clinical trials for our product candidates;Â Â·our ability to raise additional capital on favorableterms and the impact of such activities on our stockholders and stock price;Â Â·our ability to generate any revenue or to continueas a going concern;Â Â·our ability to execute our research and developmentplan on time and on budget;Â Â·our product candidatesâ€™ ability to demonstrateefficacy or an acceptable safety profile;Â Â·our ability to obtain the support of qualifiedscientific collaborators;Â Â·our ability, whether alone or with commercialpartners, to successfully commercialize any of our product candidates that may be approved for sale;Â Â·our ability to identify and obtain additionalproduct candidates;Â Â·our reliance on third parties in non-clinicalstudies and clinical trials;Â Â·our ability to defend against product liabilityclaims;Â Â·our ability to safeguard against security breaches;Â Â·our ability to obtain and maintain sufficientintellectual property protection for our product candidates;Â Â·our ability to comply with our intellectual propertylicensing agreements;Â Â·our ability to defend against claims of intellectualproperty infringement;Â Â·our ability to comply with the maintenance requirementsof the government patent agencies;Â Â·our ability to protect our intellectual propertyrights throughout the world;Â Â·competition;Â Â·the anticipated start dates, durations and completiondates of our ongoing and future clinical trials;Â iv Â Â Â·the anticipated designs of our future clinicaltrials;Â Â·our ability to attract and retain qualified employees;Â Â·the impact of Fast Track designation on receiptof actual FDA approval;Â Â·our anticipated future regulatory submissionsand our ability to receive regulatory approvals to develop and market our product candidates, including any orphan drug or Fast Trackdesignations; and Â Â·our anticipated future cash position and abilityto obtain funding for our operations. Â We have based these forward-looking statements largelyon our current expectations and projections about future events, including the responses we expect from the U.S. Food and Drug Administration,(â€œFDAâ€), and other regulatory authorities and financial trends that we believe may affect our financial condition, resultsof operations, business strategy, preclinical studies and clinical trials, and financial needs. These forward-looking statements are subjectto a number of risks, uncertainties and assumptions including, without limitation, the risks described in â€œRisk Factorsâ€ inPart 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-Kinclude additional factors which could adversely impact our business and financial performance. Moreover, we operate in a very competitiveand rapidly changing environment. New risk factors emerge from time to time and it is not possible for our management to predict all riskfactors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, maycause actual results to differ materially from those contained in any forward-looking statements. You should not rely upon forward-lookingstatements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward-looking statementswill be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except asrequired by applicable laws including the securities laws of the United States, we assume no obligation to update or supplement forward-lookingstatements.Â As used in this Annual Report on Form 10-K, the termsâ€œwe,â€ â€œus,â€ â€œour,â€ â€œCompanyâ€ and â€œAnavexâ€ mean Anavex Life Sciences Corp.,unless the context clearly requires otherwise.Â v Â Â PART IÂ ITEM 1. BUSINESSÂ Overview and StrategyÂ Anavex Life Sciences Corp. is a clinical stage

biopharmaceuticalcompany engaged in the development of differentiated therapeutics by applying precision medicine to central nervous system (â€œCNSâ€)diseases with high unmet need. We analyze genomic data from clinical trials to identify biomarkers, which we use in the analysis of ourclinical trials.Â Our focus is on developing innovativetreatments for Alzheimerâ€™s disease, Parkinsonâ€™s disease, schizophrenia, neurodevelopmental, neurodegenerative, and rare diseases,including Rett syndrome, and other central nervous system (CNS) disorders.Â 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.Â The following table summarizes key information about our programs:Â Â * = Orphan Drug Designation by the FDA Â Anavex has a portfolio of compounds varying in sigma-1receptor (SIGMAR1) binding activities. The SIGMAR1 gene encodes the SIGMAR1 protein, which is an intracellular chaperone protein withimportant roles in cellular communication. SIGMAR1 is also involved in transcriptional regulation at the nuclear envelope and restoreshomeostasis and stimulates recovery of cell function when activated. In order to validate the ability of our compounds to activate quantitativelythe SIGMAR1, we performed, in collaboration with Stanford University, a quantitative Positron Emission Tomography (PET) imaging scan inmice, which demonstrated a dose-dependent ANAVEXÂ®2-73 (blarcamesine) target engagement or receptor occupancy with SIGMAR1in the brain.Â 6 Â Â Â Source: Reyes S et al., Sci Rep. 2021 Aug 25;11(1):17150Â Cellular HomeostasisÂ Many diseases are possibly directly caused by chronichomeostatic imbalances or cellular stress of brain cells. In pediatric diseases, such as Rett syndrome or infantile spasms, chronic cellularstress is possibly caused by the presence of a constant genetic mutation. In neurodegenerative diseases, such as Alzheimerâ€™s andParkinsonâ€™s diseases, chronic cellular stress is possibly caused by age-correlated buildup of cellular insult and hence chroniccellular stress. Specifically, defects in homeostasis of protein or ribonucleic acid (â€œRNAâ€) lead to the death of neuronsand dysfunction of the nervous system. The spreading of protein aggregates resulting in a proteinopathy, a characteristic found in Alzheimerâ€™sand Parkinsonâ€™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 innerve cells. For example, Alzheimerâ€™s disease pathology is characterized by the presence of amyloid plaques, and neurofibrillarytangles, which are aggregates of hyperphosphorylated Tau protein that are a marker of other diseases known as tauopathies as well as inflammationof microglia. With the SIGMAR1 activation through SIGMAR1 agonists like ANAVEXÂ®2-73 (blarcamesine), our approach is torestore cellular balance (i.e. homeostasis). Therapies that correct defects in cellular homeostasis might have the potential to halt ordelay neurodevelopmental and neurodegenerative disease progression.Â 7 Â Â ANAVEXÂ®2-73 (blarcamesine)-specificBiomarkersÂ As part of some of our clinical trials, we have incorporateda genomic analysis to better understand potential populations for whom our clinical programs might benefit. In our clinical trials, afull genomic analysis of Alzheimerâ€™s disease patients treated with ANAVEXÂ®2-73 (blarcamesine) has helped us identifyactionable genetic variants. A significant impact of the genomic biomarkers SIGMAR1, the direct target of ANAVEXÂ®2-73 (blarcamesine)and COMT, a gene involved in memory function, on the drug response level was identified, leading to an early ANAVEXÂ®2-73(blarcamesine) specific biomarker hypothesis. We believe that excluding patients with SIGMAR1 identified biomarker variant (approximately10%-20% of the population) in prospective studies would identify approximately 80%-90% patients that would display clinically significantimproved functional and cognitive scores. The consistency between the identified DNA and RNA data related to ANAVEXÂ®2-73(blarcamesine), which are considered independent of Alzheimerâ€™s disease pathology, as well as multiple endpoints and time-points,provides support for the potential precision medicine clinical development of ANAVEXÂ®2-73 (blarcamesine) by using geneticbiomarkers identified within the trial population itself to either confirm the mechanism of action of ANAVEXÂ®2-73 (blarcamesine)or target patients who are most likely to respond to ANAVEXÂ®2-73 (blarcamesine) treatment. We may in the future utilizesuch an approach in Alzheimerâ€™s disease as well as indications like Parkinsonâ€™s disease dementia in which ANAVEXÂ®2-73(blarcamesine) is currently being studied.Â Clinical Trials OverviewÂ Alzheimerâ€™s DiseaseÂ In November 2016, we completed a Phase 2a clinicaltrial, consisting of Part A and Part B, which lasted a total of 57 weeks, for ANAVEXÂ®2-73 in mild-to-moderate Alzheimerâ€™spatients. This open-label randomized trial in Australia met both primary and secondary endpoints and was designed to assess the safetyand exploratory efficacy of ANAVEXÂ®2-73 in 32 patients. ANAVEXÂ®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 reversethe pathological hallmarks observed in Alzheimerâ€™s disease. In October 2017, we presented positive pharmacokinetic (â€œPKâ€)and pharmacodynamic (â€œPDâ€) data from the Phase 2a clinical trial, which established a concentration-effect relationship betweenANAVEXÂ®2-73 and trial measurements. These measures obtained from all patients who participated in the entire 57 weeks includeexploratory cognitive and functional scores as well as biomarker signals of brain activity. Additionally, the clinical trial appearedto show that ANAVEXÂ®2-73 activity was enhanced by its active metabolite (ANAVEX19-144), which also targets the SIGMAR1receptor and has a half-life approximately twice as long as the parent molecule.Â Two consecutive trial extensions for the Phase 2atrial have allowed participants who completed the 52-week Part B of the trial to continue taking ANAVEXÂ®2-73, providingan opportunity to gather extended safety data for a cumulative time period of five years. In August 2020, patients completing these Phase2a trial extensions were granted continued access to treatment with ANAVEXÂ®2-73 through the Australian Government Departmentof Health â€“ Therapeutic Goods Administrationâ€™s compassionate use Special Access Scheme.Â A larger Phase 2b/3 double-blind, placebo-controlledtrial of ANAVEXÂ®2-73 in early Alzheimerâ€™s disease commenced in August 2018. The Phase 2b/3 trial enrolled 508 patients,which were treated with a convenient once-daily oral formulation of ANAVEXÂ®2-73 for 48 weeks, randomized 1:1:1 to two differentANAVEXÂ®2-73 doses or placebo. The trial took place at 52 sites across North America, Europe and Australia. Primary andsecondary endpoints to assess safety and both cognitive and functional efficacy, were measured through the Alzheimerâ€™s Disease AssessmentScale â€“ Cognitive Subscale test (â€œADAS-Cogâ€), Alzheimerâ€™s Disease Cooperative Study â€“ Activities of DailyLiving (â€œADCS-ADLâ€) and Clinical Dementia Rating â€“ Sum of Boxes for cognition and function (â€œCDR-SBâ€). Inaddition to these endpoints, the ANAVEXÂ®2-73 Phase 2b/3 trial design incorporated pre-specified statistical analyses relatedto potential genomic precision medicine biomarkers previously identified in the ANAVEXÂ®2-73 Phase 2a clinical trial. Thetrial was completed in mid-2022 and, in December 2022, the Company presented topline results from the Phase 2b/3 clinical trial. All statisticalanalyses were performed by outside consultancy companies.Â 8 Â Â Furthermore, all pre-specified clinical endpoints were analyzed using a mixed modelfor repeated measures (MMRM). Under the multiplicity control rule, a trial is successful in meeting the co-primary endpoints if the significanceof each endpoint is $P < 0.05$, or if the significance of only one co-primary endpoint is $P < 0.025$. If only one primary endpointis significant at an Î± level of 0.025, then the secondary endpoint will be

evaluated at the same level of 0.025. The trial was successful,the differences in the least-squares mean (LSM) change from baseline to 48 weeks between the ANAVEXÂ®2-73 and placebo groupsfor ADAS-Cog13 was significant at a level of P < 0.025 and for CDR-SB was significant at a level of P < 0.025, in the patients withearly Alzheimerâ€™s disease.Â The comparison of individual dose groups vs placeboalso supports blarcamesineâ€™s efficacy. For the primary endpoint ADAS-Cog13, blarcamesine is significantly better than placebo (âˆ’2.027;P = 0.0079) as well as for both the 50 mg (âˆ’2.149; P = 0.021) and the 30 mg (âˆ’1.934; P = 0.026) blarcamesine dosage groupsat Week 48, representing that blarcamesine slowed clinical progression at 48 weeks by 36.3% and by 38.5% and 34.6% in 50 mg and 30 mggroups vs. placebo, respectively. The functional co-primary endpoint, ADCS-ADL, was trending in a positive direction but did not reachsignificance at Week 48. The key secondary endpoint CDR-SB was significantly improved vs. placebo (âˆ’0.483, P = 0.0104) as well asin both 50 mg (âˆ’0.465; P = 0.045) and 30 mg (âˆ’0.502; P = 0.020) groups at Week 48. Clinical Global Impression â€“ Improvement(â€œCGI-Iâ€) was also significantly improved vs. placebo (âˆ’0.278, P = 0.004) as well as in both the 50 mg (âˆ’0.314;P = 0.008) and the 30 mg (âˆ’0.248; P = 0.024) groups at Week 48. The findings are supported by biomarkers, including plasma AÎ²42/40-ratioand reduction of brain atrophy. Blarcamesine significantly slowed brain atrophy in key regions of interest, including the whole brainby 37.6%, total grey matter by 63.5%, and lateral ventricles by 25.1%.Â In the respective safety population, common treatment-emergentadverse events included dizziness, which was transient and mostly mild to moderate in severity, and occurred in 120 participants (35.8%)during titration and in 76 participants (25.2%) during maintenance with ANAVEXÂ®2-73 and 10 (6.0%) during titration and9 (5.6%) during maintenance with placebo.Â In November 2024, we announced the submission of aMarketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for ANAVEXÂ®2-73 for the treatment ofAlzheimer's disease and, in December 2024, the EMA accepted the submission for scientific review. The MAA, if approved, would allow directmarket access throughout the European Union for oral ANAVEXÂ®2-73 (blarcamesine) for the treatment of Alzheimerâ€™sdisease.Â A subsequent long-term open label extension studyof ANAVEXÂ®2-73, referred to as the ATTENTION-AD trial, was initiated for patients who completed the 48-week Phase 2b/3placebo-controlled trial referenced above. This trial extension for a duration of up to 96/144 additional weeks was completed in June2024. The trial extension will provide additional longer-term safety and efficacy data of ANAVEXÂ®2-73 in persons with earlyAlzheimerâ€™s disease.Â Rett Syndrome Â In February 2016, we presented positive preclinicaldata for ANAVEXÂ®2-73 in Rett syndrome, a rare neurodevelopmental disease. The data demonstrated dose related significantimprovements in an array of behavioral and gait paradigms in a mouse model with an MECP2-null mutation that causes neurological symptomsthat mimic Rett syndrome. The study was funded by the International Rett Syndrome Foundation (â€œRettsyndrome.orgâ€). In January2017, we were awarded a financial grant from Rettsyndrome.org of a minimum of $0.6 million to cover some of the costs of a multicenterPhase 2 clinical trial of ANAVEXÂ®2-73 for the treatment of Rett syndrome.Â In March 2019, we commenced the first Phase 2clinical trial in a planned Rett syndrome program of ANAVEXÂ®2-73 for the treatment of Rett syndrome. The clinicaltrials were conducted in a range of patient age demographics and geographic regions, utilizing an oral liquid once-daily formulationof ANAVEXÂ®2-73.Â The first Phase 2 trial, (ANAVEXÂ®2-73-RS-001),which took place in the United States, was completed in December 2020. This trial was a randomized double-blind, placebo-controlled safety,tolerability, PK and efficacy trial of oral liquid ANAVEXÂ®2-73 formulation in 25 adult female patients with Rett syndromeover a 7-week treatment period including ANAVEXÂ®2-73-specific genomic precision medicine biomarkers. The primary endpointof the trial was safety. The dosing of 5 mg ANAVEXÂ®2-73 was well-tolerated and demonstrated dose-proportional PK. All secondaryefficacy endpoints of the trial showed statistically significant and clinically meaningful response in the Rett Syndrome Behaviour Questionnaire(â€œRSBQâ€) response, when compared to placebo, in the intent to treat (â€œITTâ€) cohort (all participants, p = 0.011).66.7% of ANAVEXÂ®2-73 treated subjects showed a statistically significant improvement in RSBQ response as compared to 10%of the subjects on placebo in the ITT cohort (all participants, p = 0.011). ANAVEXÂ®2-73 treatment resulted in a sustainedimprovement in CGI-I response throughout the 7-week clinical trial, when compared to placebo in the ITT cohort (all participants, p =0.014). Consistent with previous ANAVEXÂ®2-73 clinical trials, patients carrying the common form of the SIGMAR1 gene treatedwith ANAVEXÂ®2-73 experienced stronger improvements in the prespecified efficacy endpoints. No other clinical trials withANAVEXÂ®2-73 related to Rett syndrome have been conducted in the United States.Â 9 Â Â Thesecond, international trial of ANAVEXÂ®2-73 for the treatment of Rett syndrome, called the AVATAR trial, commenced in June2019. This trial took place in Australia and the United Kingdom using a higher dose than the U.S. based Phase 2 trial for Rettsyndrome. The trial was a Phase 3 randomized, double-blind, placebo-controlled trial to evaluate the safety and efficacy of ANAVEXÂ®2-73in 33 adult patients over a 7-week treatment period including ANAVEXÂ®2-73 specific precision medicine biomarkers. Basedupon the input from the successful U.S. Phase 2 Rett syndrome trial (ANAVEXÂ®2-73-RS-001), we updated the endpoints forthe AVATAR trial (ANAVEXÂ®2-73-RS-002) to appropriately assess the clinically meaningful outcome following InternationalConference on Harmonization (ICH) guidelines. These updates were approved by the respective regulatory authorities in the U.K. and inAustralia, respectively, where the AVATAR trial was conducted.Â The data from the AVATAR trial was released in February2022. The clinical trial met all primary and secondary efficacy and safety endpoints, with consistent improvements in primary efficacyendpoint, RSBQ response (p = 0.037), and secondary efficacy endpoints, Anxiety, Depression, and Mood Scale (ADAMS) (p = 0.010) and CGI-I(p = 0.037) response. Efficacy endpoints demonstrated statistically significant and clinically meaningful reductions in Rett syndromesymptoms. Convenient once daily oral liquid doses of up to 30 mg of ANAVEXÂ®2-73 were also well tolerated with good medicationcompliance. All patients who participated in the trial were eligible to receive ANAVEXÂ®2-73 under a voluntary open labelextension protocol and subsequent Compassionate Use Program.Â The very first trial of ANAVEXÂ®2-73in pediatric Rett syndrome patients, the EXCELLENCE trial, completed enrollment in February 2023. This randomized, double-blind, placebo-controlledPhase 2/3 trial in pediatric patients with Rett syndrome included trial sites in Canada, Australia, and the United Kingdom. 92 pediatricpatients with Rett syndrome between the ages of 5 through 17 years were treated daily with up to 30 mg ANAVEXÂ®2-73. Participantswere randomized 2:1 (ANAVEXÂ®2-73:placebo) for 12 weeks, followed by a week 16 safety visit and topline results from thistrial were announced in early January 2024.Â After 12 weeks, the study showed improvement on thekey co-primary endpoint RSBQ, which is a detailed 45-item questionnaire for assessing multiple Rett syndrome characteristics by the patientsâ€™caregivers. The other co-primary endpoint, the CGI-I, which represents a less granular assessment by the site investigators using a seven-pointscoring (one=â€œvery much improvedâ€ to seven=â€œvery much worseâ€), was not met.Â In an ad-hoc analysis, using the predefined mixed-effectmodel for repeated measure (MMRM) method, after 12 weeks of treatment, ANAVEXÂ®2-73-treated patients improved LS Mean (SE)-12.93 (2.150) points on their RSBQ total score compared to LS Mean (SE) -8.32 (2.537) points

in placebo-treated patients. The LS Meandifference (SE) of -4.61 (2.439) points between treated and placebo groups did not reach statistical significance (n=77; p=0.063). ANAVEXÂ®2-73-treatedpatients demonstrated a rapid onset of action with improvements at 4 weeks after treatment with a RSBQ total score LS Mean (SE) -10.32(2.086) points in the drug-treated group compared to a LS Mean (SE) -5.67 (2.413) points in placebo-treated patients. The LS Mean differenceof -4.65 (2.233) points between treated and placebo groups was statistically significant (n=77; p=0.041).Â The key secondary endpoint, the ADAMS, trended favorably.In the same analysis, scores for all RSBQ and ADAMS subscales improved over the course of the study. Collectively, the RSBQ and ADAMSdemonstrated improvements in multiple areas, impacting positively in particular repetitive movements, nighttime disruptive behaviors,and social avoidance.Â A preliminary review of the safety results indicatesthere were no new safety signals in the EXCELLENCE study, reinforcing the favorable and manageable safety profile observed with ANAVEXÂ®2-73to date.Â All patients who participated in the trial were eligibleto receive ANAVEXÂ®2-73 under a voluntary open label extension protocol, which was completed in June 2024.Â A high enrollment rate in the Open Label Extension(â€œOLEâ€) of over 91% and the high level of requests for the Compassionate Use Program (93%) provide solid numerical evidencefor the reported positive Real World Evidence (RWE) from patients with Rett syndrome under Compassionate Use Authorization. Families whosechildren were previously on drug or placebo in the placebo-controlled trial commented favorably on the improvement of their childâ€™sdaily life due to ANAVEXÂ®2-73 treatment in the Compassionate Use Program.Â 10 Â Â Parkinsonâ€™s DiseaseÂ In September 2016, we presented positive preclinicaldata for ANAVEXÂ®2-73 in an animal model of Parkinsonâ€™s disease, which demonstrated significant improvements on behavioral,histopathological, and neuroinflammatory endpoints. The study was funded by the Michael J. Fox Foundation. Additional data announced inOctober 2017 indicated that ANAVEXÂ®2-73 induced robust neurorestoration in experimental Parkinsonism. We believe the encouragingresults we have gathered in this preclinical model, coupled with the favorable profile of this product candidate in the Alzheimerâ€™sdisease trial, support the notion that ANAVEXÂ®2-73 has the potential to treat Parkinsonâ€™s disease dementia.Â In October 2020, we completed a double-blind, randomized,placebo-controlled proof-of-concept Phase 2 trial with ANAVEXÂ®2-73 in Parkinsonâ€™s disease dementia in Spain and Australia,to study the effect of the compound on both the cognitive and motor impairment of Parkinsonâ€™s disease. The Phase 2 trial enrolledapproximately 132 patients for 14 weeks, randomized 1:1:1 to two different ANAVEXÂ®2-73 doses, 30 mg and 50 mg, or placebo.The ANAVEXÂ®2-73 Phase 2 Parkinsonâ€™s disease dementia trial design incorporated genomic precision medicine biomarkersidentified in the ANAVEXÂ®2-73 Phase 2a Alzheimerâ€™s disease trial.Â The trial demonstrated that ANAVEXÂ®2-73was safe and well tolerated in oral doses up to 50 mg once daily. The results showed clinically meaningful, dose-dependent, and statisticallysignificant improvements in the Cognitive Drug Research (â€œCDRâ€) computerized assessment system analysis. Treatment with ANAVEXÂ®2-73also resulted in clinically meaningful improvements as measured by the global composite score of Parkinsonâ€™s disease symptom severity,MDS-Unified Parkinsonâ€™s Disease Rating Scale (â€œMDS-UPDRSâ€) total score on top of standard of care including dopaminergictherapy, levodopa and other anti-PD medications after 14 weeks of treatment, suggesting ANAVEXÂ®2-73â€™s potential capabilityof slowing and reversing symptoms that progress in Parkinsonâ€™s disease. In addition, the trial confirmed the precision medicineapproach of targeting SIGMAR1 as a genetic biomarker in response to ANAVEXÂ®2-73 may result in improved clinical outcomes.Â A 48-week OLE ANAVEX2-73-PDD-EP-001 Phase 2 trialwas offered to participants after completion of the double-blind placebo-controlled ANAVEX2-73-PDD-001 Phase 2 trial discussed above.The OLE trial assessed safety, tolerability and efficacy, measuring among others, MDS-Unified Parkinsonâ€™s Disease Rating Scale PartsI, II, III, REM Sleep Behavior Disorder Screening Questionnaire (RBDSQ), CGI-I, as well as cognitive efficacy endpoint Montreal CognitiveAssessment (MoCA) over a 48-week period.Â In March 2023, we reported the preliminary ANAVEX2-73-PDD-EP-001OLE trial data, which demonstrated longitudinal beneficial effects of ANAVEXÂ®2-73 on the pre-specified primary and secondaryobjectives. Preliminary analysis reveals that ANAVEXÂ®2-73 was found to be generally safe and well tolerated, and safetyfindings in this trial were consistent with the known safety profile of ANAVEXÂ®2-73. In respect to efficacy, across allefficacy endpoints, patients performed better while on ANAVEXÂ®2-73. While all patients were on drug holiday due to COVID-19between the DB EOT and the OLE Baseline, the respective efficacy endpoints, including the MDS-UPDRS Part II + III and CGI-I, measuredat the end of trial of the double-blind study (DB EOT) and the OLE Baseline, were worsening, as expected in a progressive disease likeParkinsonâ€™s. However, when patients resumed daily oral ANAVEXÂ®2-73 treatment, a consistent improvement was observedduring the extension phase from OLE Baseline through OLE Week 24, and OLE Week 48, respectively. These results are consistent with thepattern observed for all efficacy measures in the extension phase. The two endpoints, MDS-UPDRS Part II + III and CGI-I measured in thisstudy are the planned primary and key secondary endpoints in our forthcoming >6-month Parkinsonâ€™s disease study.Â In January 2021, we were awarded a research grantof $1.0 million fromÂ The Michael J. Fox Foundation for Parkinsonâ€™s ResearchÂ to develop ANAVEXÂ®2-73 forthe treatment of Parkinsonâ€™s disease. The award will explore utilization of PET imaging biomarkers to enable measurement of targetengagement and pathway activation of the SIGMAR1 with clinically relevant doses including in people with Parkinsonâ€™s disease.Â 11 Â Â Schizophrenia, Frontotemporal Dementia and Alzheimerâ€™sdiseaseÂ In July 2020, we commenced the First-in-Human Phase1 clinical trial of ANAVEXÂ®3-71. ANAVEXÂ®3-71 was previously granted orphan drug designation for the treatmentof Frontotemporal Dementia (â€œFTDâ€) by the FDA. ANAVEXÂ®3-71 is an orally administered small molecule targetingsigma-1 and M1 muscarinic receptors that is designed to be beneficial for neurodegenerative diseases. In preclinical studies, ANAVEXÂ®3-71demonstrated disease-modifying activity against the major hallmarks of Alzheimerâ€™s disease in transgenic (3xTg-AD) mice, includingcognitive deficits, amyloid and tau pathologies, as well as beneficial effects on mitochondrial dysfunction and neuroinflammation.Â The Phase 1clinical trial was a prospective double-blind, randomized, placebo-controlled trial in Australia. A total of 36 healthy male and femalesubjects were included. Single escalating doses of ANAVEXÂ®3-71 were administered in order to evaluate the safety, tolerability,and PK of ANAVEXÂ®3-71 and the effects of food and gender on its PK in healthy volunteers. Â The trial metits primary and secondary endpoints of safety, with no serious adverse events (â€œSAEsâ€) or dose-limiting toxicities observed.ANAVEXÂ®3-71 was well tolerated in all cohorts receiving ANAVEXÂ®3-71 in single doses ranging from 5 mg to200 mg daily with no SAEs and no significant lab abnormalities in any subject. In the trial, ANAVEXÂ®3-71 exhibited linearPK. Its pharmacokinetics was also dose proportional for doses up to 160 mg. Gender had no effect on the PK of the drug and food had noeffect on the bioavailability of ANAVEXÂ®3-71. The trial also met the secondary objective of characterizing the effect ofANAVEXÂ®3-71 on electrocardiogram (â€œECGâ€) parameters. There were no clinically significant ECG parameters throughoutthe trial. Participant QTcF measures were normal across all dose groups with no difference between ANAVEXÂ®3-71 and placebo.Â In October 2023a peer-reviewed publication in the

journal Neurobiology of Aging, titled â€˜Early treatment with an M1 and sigma-1 receptoragonist prevents cognitive decline in a transgenic rat model displaying Alzheimer-like amyloid pathologyâ€™, featured the orallyavailable small molecule ANAVEXÂ®3-71 (AF710B). The preclinical study described the potential disease-modifying propertiesof ANAVEXÂ®3-71 on Alzheimerâ€™s disease pathology as a possible drug candidate for a potential once daily oral preventivestrategy for Alzheimerâ€™s disease.Â In January 2024,in another peer-reviewed publication in the journal Clinical Pharmacology in Drug Development, entitled, â€˜Population-BasedCharacterization of the Pharmacokinetics and Food Effect of ANAVEX3-71, a Novel Sigma-1 Receptor and Allosteric M1 Muscarinic ReceptorAgonist in Development for Treatment of Frontotemporal Dementia, Schizophrenia, and Alzheimer Diseaseâ€™, reported the population-basedcharacterization of the PK and food effect of ANAVEXÂ®3-71 as part of the single ascending dose study in healthy participantswith the primary objective of assessing dose proportionality of ANAVEXÂ®3-71, and to characterize the effect of food onthe PK of ANAVEXÂ®3-71. The results from this PK evaluation demonstrated that ANAVEXÂ®3-71, at single ascendingdoses of 5 to 200 mg, is linear, dose proportional, and time invariant. Food had no effect on the PK of ANAVEXÂ®3-71. Thisdata also expands the safety objectives met in this first-in-human study of ANAVEXÂ®3-71, further supporting its drug developmentprogram.Â Based on theseresults, and ANAVEXÂ®3-71â€™s pre-clinical profile, we intend to advance ANAVEXÂ®3-71 into a biomarker-drivenclinical development dementia program for the treatment of schizophrenia, FTD and Alzheimerâ€™s disease, evaluating longitudinal effectof treatment with ANAVEXÂ®3-71.Â SchizophreniaÂ In March 2024,we commenced the U.S. FDA-cleared ANAVEXÂ®3-71-SZ-001 clinical trial: a double-blind, placebo-controlled Phase 2 trial inschizophrenia. The trial consists of two parts to explore multiple ascending doses in individuals with schizophrenia followed by a 28-daytreatment period in a larger cohort. The trial will utilize standard clinical outcome measures for schizophrenia including the Positiveand Negative Symptoms Scale (PANSS), and novel fluid and electrophysiological biomarkers will also be assessed, leveraging several advancesin electroencephalography/event-related potential (EEG/ERP) biomarkers in schizophrenia developed in collaboration with the industry-ledERP Biomarker Qualification Consortium. In addition to the electrophysiological biomarkers, we are also applying novel neuroinflammatory,metabolomic, and transcriptomic biomarkers at the intersection of schizophrenia pathophysiology and ANAVEXÂ®3-71â€™snovel, dual mechanism of action.Â 12 Â Â Preliminaryresults from Part A of the ANAVEXÂ®3-71-SZ-001 clinical trial, consisting of a multiple ascending dose study in 16 participants,demonstrated a dose-dependent effect of ANAVEXÂ®3-71 on two key EEG biomarkers in patients with schizophrenia. The effectswere most pronounced in the higher dose group indicating a dose-dependent pharmacodynamic effect. The observed changes reversed knownelectroencephalography (EEG) and ERP biomarker abnormalities associated with schizophrenia. These EEG biomarkers correlate with positive,negative, and cognitive symptoms of schizophrenia. Â The currentlyongoing Part B of the placebo-controlled Phase 2 study, which includes more participants and a longer treatment duration, will providemore comprehensive data on the efficacy and safety of ANAVEXÂ®3-71 in schizophrenia.Â Our PipelineÂ Our research and development pipeline includes ANAVEXÂ®2-73currently in three different clinical trial indications, and ANAVEXÂ®3-71 currently in one clinical trial and several othercompounds in different stages of clinical and pre-clinical development.Â Our proprietary SIGMACEPTORâ„¢ Discovery Platformproduced small molecule drug candidates with unique modes of action, based on our understanding of sigma receptors. Sigma receptors maybe targets for therapeutics to combat many human diseases, both of neurodegenerative nature, including Alzheimerâ€™s disease, as wellas of neurodevelopmental nature, like Rett syndrome. When bound by the appropriate ligands, sigma receptors influence the functioningof 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 survivaland replication. Hence, it is possible that SIGMAR1 could play a role in modulating the cellular response to viral infection and amelioratepathogenesis.Â Compounds that have been subjects of our researchinclude the following:Â ANAVEXÂ®2-73 (blarcamesine)Â We believe ANAVEXÂ®2-73 may offer adisease-modifying approach in neurodegenerative and neurodevelopmental diseases by activation of SIGMAR1. ANAVEXÂ®2-73 isbeing developed in an oral liquid once-daily formulation for rare diseases such as Rett syndrome as well as an oral once-daily capsuleformulation for diseases such as Alzheimerâ€™s disease.Â In Rett syndrome, administration of ANAVEXÂ®2-73in liquid form resulted in both significant and dose-related improvements in an array of behavioral paradigms in the MECP2 HET Rett syndromedisease model. In addition, in a further experiment sponsored by Rettsyndrome.org, ANAVEXÂ®2-73 was evaluated in automaticvisual response and respiration tests in 7-month-old mice, an age at which advanced pathology is evident. Vehicle-treated MECP2 mice demonstratedfewer automatic visual responses than wild-type mice. Treatment with ANAVEXÂ®2-73 for four weeks significantly increasedthe automatic visual response in the MECP2 Rett syndrome disease mice. Additionally, chronic oral dosing daily for 6.5 weeks of ANAVEXÂ®2-73starting at ~5.5 weeks of age was conducted in the MECP2 HET Rett syndrome disease mouse model assessed the different aspects of musculorcoordination, balance, motor learning and muscular strengths, some of the core deficits observed in Rett syndrome. Administration of ANAVEXÂ®2-73resulted in both significant and dose related improvements in an array of these behavioral paradigms in the MECP2 HET Rett syndrome diseasemodel.Â In May 2016 and June 2016, the FDA granted OrphanDrug Designation to ANAVEXÂ®2-73 for the treatment of Rett syndrome and infantile spasms, respectively. In November 2019,the FDA granted ANAVEXÂ®2-73 the Rare Pediatric Disease (RPD) designation for the treatment of Rett syndrome. The RPD designationis intended to encourage the development of treatments for rare pediatric diseases.Â Further, in February 2020, the FDA granted Fast Trackdesignation for the ANAVEXÂ®2-73 clinical development program for the treatment of Rett syndrome. The FDA Fast Track programis designed to facilitate and expedite the development and review of new drugs to address unmet medical needs in the treatment of seriousand life-threatening conditions.Â 13 Â Â For Parkinsonâ€™s disease, data demonstrates significantimprovements and restoration of function in a disease modifying animal model of Parkinsonâ€™s disease. Significant improvements wereseen 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 ANAVEXÂ®2-73 in Parkinsonâ€™s disease dementia, tostudy the effect of the compound on both the cognitive and motor impairment of Parkinsonâ€™s disease. The Phase 2 trial enrolled approximately132 patients for 14 weeks, randomized 1:1:1 to two different ANAVEXÂ®2-73 doses, 30 mg and 50 mg, or placebo. The ANAVEXÂ®2-73Phase 2 Parkinsonâ€™s disease dementia trial design incorporated genomic precision medicine biomarkers identified in the ANAVEXÂ®2-73Phase 2a Alzheimerâ€™s disease trial.Â The trial demonstrated that ANAVEXÂ®2-73was safe and well tolerated in oral doses up to 50 mg once daily. The results showed clinically meaningful, dose-dependent, and statisticallysignificant improvements in the CDR computerized assessment system analysis. We anticipate conducting further clinical trials of ANAVEXÂ®2-73in Parkinsonâ€™s disease dementia after submitting the results of the trial to regulatory authorities to

obtain regulatory guidance.Â In Alzheimerâ€™s disease animal models, ANAVEXÂ®2-73has shown pharmacological, histological and behavioral evidence as a potential neuroprotective, anti-amnesic, anti-convulsive and anti-depressivetherapeutic agent, due to its potent affinity to SIGMAR1 and moderate affinities to M1-4 type muscarinic receptors. In addition, ANAVEXÂ®2-73has shown a potential dual mechanism which may impact amyloid, tau pathology and inflammation. In a transgenic Alzheimerâ€™s diseaseanimal model Tg2576, ANAVEXÂ®2-73 induced a statistically significant neuroprotective effect against the development ofoxidative stress in the mouse brain, as well as significantly increased the expression of functional and synaptic plasticity markers thatis 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.Â Based on the results of pre-clinical testing, we initiatedand completed a Phase 1 single ascending dose (SAD) clinical trial of ANAVEXÂ®2-73. In this Phase 1 SAD trial, the maximumtolerated single dose was defined per protocol as 55-60 mg. This dose is above the equivalent dose shown to have positive effects in mousemodels of Alzheimerâ€™s disease. There were no significant changes in laboratory or ECG parameters. ANAVEXÂ®2-73 waswell tolerated below the 55-60 mg dose with only mild adverse events in some subjects. Observed adverse events at doses above the maximumtolerated single dose included headache and dizziness, which were moderate in severity and reversible. These side effects are often seenwith drugs that target CNS conditions, including Alzheimerâ€™s disease.Â In November 2016, we completed a Phase 2a clinicaltrial for ANAVEXÂ®2-73, for the treatment of Alzheimerâ€™s disease. The open-label randomized trial was designed toassess the safety and exploratory efficacy of ANAVEXÂ®2-73 in 32 patients with mild-to-moderate Alzheimerâ€™s disease.The Phase 2a trial met both primary and secondary objectives of the trial.Â In July 2018, we presentedthe results of a genomic DNA and RNA evaluation of the participants in the Phase 2a clinical trial. More than 33,000 genes were analyzedusing unbiased, data driven, machine learning, artificial intelligence (AI) system for analyzing DNA and RNA data in patients treatedwith ANAVEXÂ®2-73. The analysis identified genetic variants that impacted response to ANAVEXÂ®2-73, amongthem variants related to the SIGMAR1, the target for ANAVEXÂ®2-73. Results showed that trial participants with the commonSIGMAR1 wild type gene variant, which is estimated to be about 80% of the population worldwide, demonstrated improved cognitive (MMSE)and functional (ADCS-ADL) scores. The results from this evaluation supported the continued evaluation of genomic information in subsequentclinical trials, since these signatures can now be applied to neurological indications tested in future clinical trials with ANAVEXÂ®2-73including Alzheimerâ€™s disease, Parkinsonâ€™s disease dementia and Rett syndrome.Â ANAVEXÂ®2-73data met prerequisite information in order to progress into a Phase 2b/3 placebo-controlled trial. On July 2, 2018, the Human ResearchEthics Committee in Australia approved the initiation of our Phase 2b/3, double-blind, randomized, placebo-controlled 48-week safety andefficacy trial of ANAVEXÂ®2-73 for the treatment of early Alzheimerâ€™s disease. Clinical trial sites in Canada, theUnited Kingdom, the Netherlands and Germany were also added. This Phase 2b/3 trial design incorporates inclusion of genomic precisionmedicine biomarkers identified in the ANAVEXÂ®2-73 Phase 2a trial.Â 14 Â Â We believe preclinical data from our studies alsosupports further research into the use of ANAVEXÂ®2-73 as a potential platform drug for other neurodegenerative diseasesbeyond Alzheimerâ€™s disease, Parkinsonâ€™s disease or Rett syndrome, more specifically, epilepsy, infantile spasms, Fragile Xsyndrome, Angelman syndrome, multiple sclerosis, and tuberous sclerosis complex (TSC). ANAVEXÂ®2-73 demonstrated significantimprovements in all of these indications in the respective preclinical animal models.Â In a preclinical study sponsored by the Foundationfor Angelman Syndrome, ANAVEXÂ®2-73 was assessed in a mouse model for the development of audiogenic seizures. The resultsindicated that ANAVEXÂ®2-73 administration significantly reduced audiogenic-induced seizures in mice. In a study sponsoredby FRAXA Research Foundation regarding Fragile X syndrome, data demonstrated that ANAVEXÂ®2-73 restored hippocampal brain-derivedneurotrophic factor (BDNF) expression to normal levels. BDNF under-expression has been observed in many neurodevelopmental and neurodegenerativepathologies. BDNF signaling promotes maturation of both excitatory and inhibitory synapses. ANAVEXÂ®2-73 normalization ofBDNF expression could be a contributing factor for the positive preclinical data observed in both neurodevelopmental and neurodegenerativedisorders like Angelman and Fragile X syndromes.Â In addition, preclinical data to-date also indicatesthat ANAVEXÂ®2-73 has the potential to demonstrate protective effects of mitochondrial enzyme complexes during pathologicalconditions, which, if impaired, may play a role in the pathogenesis of neurodegenerative and neurodevelopmental diseases.Â In addition, preclinical data on ANAVEXÂ®2-73related to multiple sclerosis indicates that ANAVEXÂ®2-73 may promote remyelination in multiple sclerosis disease. Further,our data also demonstrates that ANAVEXÂ®2-73 has the potential to provide protection for oligodendrocytes and oligodendrocyteprecursor cells (â€œOPCsâ€), as well as central nervous system neurons in addition to helping repair by increasing OPC proliferationand maturation in tissue culture.Â In March 2018, we presented preclinical data of ANAVEXÂ®2-73in a genetic mouse model of tuberous sclerosis complex (â€œTSCâ€). TSC is a rare genetic disorder characterized by the growthof numerous benign tumors in many parts of the body with a high incidence of seizures. The preclinical data demonstrated that treatmentwith ANAVEXÂ®2-73 significantly increased survival and reduced seizures in those mice.Â ANAVEXÂ®3-71Â ANAVEXÂ®3-71 is an orally availableclinical drug candidate with a novel mechanism of action via SIGMAR1 activation and M1 muscarinic allosteric modulation, which has beenshown to enhance neuroprotection and cognition in Alzheimerâ€™s disease models. ANAVEXÂ®3-71 is a CNS-penetrable potentialdisease modifying treatment for cognitive impairments. We believe it is effective in against the major Alzheimerâ€™s hallmarks intransgenic (3xTg-AD) mice, including cognitive deficits, amyloid and tau pathologies, and also has beneficial effects on inflammationand mitochondrial dysfunctions. ANAVEXÂ®3-71 indicates extensive therapeutic advantages in Alzheimerâ€™s and other protein-aggregation-relateddiseases given its ability to enhance neuroprotection and cognition via SIGMAR1 activation and M1 muscarinic allosteric modulation.Â A preclinical study examined the response of ANAVEXÂ®3-71in aged transgenic animal models and showed a significant reduction in the rate of cognitive deficit, amyloid beta pathology and inflammationwith the administration of ANAVEXÂ®3-71. In April 2016, the FDA granted Orphan Drug Designation to ANAVEXÂ®3-71for the treatment of FTD.Â During pathological conditions ANAVEXÂ®3-71demonstrated the formation of new synapses between neurons (synaptogenesis) without causing an abnormal increase in the number of astrocytes.In neurodegenerative diseases such as Alzheimerâ€™s and Parkinsonâ€™s disease, synaptogenesis is believed to be impaired. Additionalpreclinical data presented also indicates that in addition to reducing oxidative stress, ANAVEXÂ®3-71 has the potentialto demonstrate protective effects of mitochondrial enzyme complexes during pathological conditions, which, if impaired, are believed toplay a role in the pathogenesis of neurodegenerative and neurodevelopmental diseases.Â 15 Â Â In July 2020, we commenced the first Phase 1 clinicaltrial ofÂ ANAVEXÂ®3-71. The trial took place in Australia and was a double-blind, randomized, placebo-controlled, Phase1 trial to evaluate safety and tolerability, and PK of oral escalating doses of ANAVEXÂ®3-71including effects of food and gender in healthy volunteers. The trial met its primary and

secondaryendpoints of safety, respectively, with no serious adverse events (SAEs) or dose-limiting toxicities observed, as more fully describedabove under Clinical Trials Overview â€“ Schizophrenia, Frontotemporal Dementia and Alzheimerâ€™s disease.Â Based on theseresults, and ANAVEXÂ®3-71 pre-clinical profile, the Company intends to advance ANAVEXÂ®3-71 into a biomarker-drivenclinical development dementia program for the treatment of schizophrenia, FTD and Alzheimerâ€™s disease, evaluating longitudinal effectof treatment with ANAVEXÂ®3-71. We believe the results of this clinical trial and preclinical study could serve as a basisfor advancing into respective registration trials in the U.S.Â The first ofthese trials, the ANAVEXÂ®3-71-SZ-001 clinical trial, commenced in March 2024 and is more fully described above underClinical Trials Overview â€“ Schizophrenia.Â ANAVEXÂ®1-41Â ANAVEXÂ®1-41 is a sigma-1 agonist. Pre-clinicaltests revealed significant neuroprotective benefits (i.e., protects nerve cells from degeneration or death) through the modulation ofendoplasmic reticulum, mitochondrial and oxidative stress, which damages and impairs cell viability. In addition, in animal models, ANAVEXÂ®1-41prevented 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 SIGMAR1 systems througha novel mechanism of action.Â Preclinical data presented also indicates that ANAVEXÂ®1-41has the potential to demonstrate 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.Â ANAVEXÂ®1066Â ANAVEXÂ®1066, a mixed sigma-1/sigma-2ligand, is designed for the potential treatment of neuropathic and visceral pain. ANAVEXÂ®1066 was tested in two preclinicalmodels of neuropathic and visceral pain that have been extensively validated in rats. In the chronic constriction injury model of neuropathicpain, a single oral administration of ANAVEXÂ®1066 dose-dependently restored the nociceptive threshold in the affected pawto normal levels while leaving the contralateral healthy paw unchanged. Efficacy was rapid and remained significant for two hours. Ina model of visceral pain, chronic colonic hypersensitivity was induced by injection of an inflammatory agent directly into the colon anda single oral administration of ANAVEXÂ®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 ANAVEXÂ®1066 anda favorable safety profile in a battery of behavioral measures.Â ANAVEXÂ®1037 Â ANAVEXÂ®1037 is designed for the treatmentof prostate and pancreatic cancer. It is a low molecular weight, synthetic compound exhibiting high affinity for sigma-1 receptors atnanomolar 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/healthycells and also to significantly suppress tumor growth in immune-deficient mice models. Scientific publications highlight the possibilitythat these ligands may stop tumor growth and induce selective cell death in various tumor cell lines. Sigma receptors are highly expressedin different tumor cell types. Binding by appropriate sigma-1 and/or sigma-2 ligands can induce selective apoptosis. In addition, throughtumor cell membrane reorganization and interactions with ion channels, we believe our drug candidates may play an important role in inhibitingthe processes of metastasis (spreading of cancer cells from the original site to other parts of the body), angiogenesis (the formationof new blood vessels) and tumor cell proliferation.Â 16 Â Â ANAVEXÂ®1037 is currently in the pre-clinicaland clinical testing stages of development, and there is no guarantee that the activity demonstrated in pre-clinical models will be shownin human testing.Â We continue to identify and initiate discussions withpotential strategic and commercial partners to most effectively advance our programs and increase stockholder value. Further, we may acquireor develop new intellectual property and assign, license, or otherwise transfer our intellectual property to further our goals.Â Our Target IndicationsÂ We are developing compounds with potential applicationto two broad categories and several specific indications, including:Â Central Nervous System DiseasesÂ Â â— Alzheimerâ€™s disease â€“ In 2024, an estimated 6.9 million Americans are suffering from Alzheimerâ€™s disease according to the Alzheimerâ€™s AssociationÂ®. The Alzheimerâ€™s AssociationÂ® estimates that the annual number of new cases of Alzheimerâ€™s and other dementias is projected to double by 2050. Medications on the market today treat only the symptoms of Alzheimerâ€™s disease and do not have the ability to stop its onset or its progression. We believe that there is an urgent and unmet need for both a disease modifying cure for Alzheimerâ€™s disease as well as for better symptomatic treatments. Â Â â— Parkinsonâ€™s disease â€“ Parkinsonâ€™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 deficiency of the neurotransmitter dopamine. Parkinsonâ€™s disease currently is estimated to afflict more than 10 million people worldwide, typically middle-aged and elderly people. The Parkinsonâ€™s disease market is expected to reach $11.5 billion by 2029, according to GlobalData. Â Â â— Rett syndrome â€“ 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 childâ€™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. Â Â â— Schizophrenia - Schizophrenia is a persistent and often disabling mental illness impacting how a person thinks, feels, and behaves, and affects nearly 24 million people worldwide, including 2.8 million people in the U.S., according to the World Health Organization. It is characterized by three symptom domains: positive symptoms (hallucinations and delusions), negative symptoms (difficulty enjoying life and withdrawal from others), and cognitive impairment (deficits in memory, concentration, and decision-making). In part due to limitations with current treatments, people living with schizophrenia often struggle to maintain employment, live independently, and manage relationships. While current treatments can be effective in managing select symptoms, approximately 34% of people do not respond to therapy, with an additional 50-60% experiencing only a partial improvement in symptoms or unacceptable side effects. Â Â â— Fragile X â€“ Fragile X syndrome (FXS) isthe most prevalent genetic form of intellectual disability and autism spectrum disorder, primarily affecting boys. As with most neurodevelopmentaldisorders, FXS is considered a condition of synaptic development and function. The disease has a range of clinical presentations dependingon the specific genetic changes associated with an â€œexpansionâ€ of the FMR1 gene. The disease is characterized by deficitsin long-term potentiation and homeostatic plasticity. FXS has been detected in all populations and ethnic groups. Researchers do notknow the exact number for how many Americans could have full mutation FXS. Studies estimate that the disease affects approximately 1:4,000males and 1:6,000 females. Worldwide, more than 1,400,000 people could be affected by FXS.Â

17 Â Â Â â— Depression â€“ Depression is a major cause of morbidity worldwide according to the World Health Organization. The global antidepressant drug market is projected to reach $21 billion by 2030 according to Allied Market Research. Pharmaceutical treatment for depression has been historically dominated by blockbuster brands. However, the dominance of the leading brands is waning, largely due to an increase in the number of approvals for antidepressant drugs. Â Â â— Epilepsy â€“ 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 medications that are 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. Â Â â— Neuropathic Pain â€“ 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. Â CancerÂ Â â— Malignant Melanoma â€“ Predominantly a skin cancer, malignant melanoma can also occur in melanocytes found in the bowel and the eye. Malignant melanoma accounts for a large majority of skin cancer deaths. The treatment includes surgical removal of the tumor, adjuvant treatment, chemo and immunotherapy, or radiation therapy. According to iHealthcareAnalyst, Inc. the worldwide malignant melanoma market is expected to grow to $7.5 billion by 2029. Â Â â— Prostate Cancer â€“ Specific to men, prostate cancer is a form of cancer that develops in the prostate, a gland in the male reproductive system. 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 $10.1 billion by the end of 2030 according to Market Research Future. Â Â â— Pancreatic Cancer â€“ Pancreatic cancer is a malignant neoplasm of the pancreas. In the United States, approximately 62,000 new cases of pancreatic cancer will be diagnosed this year and approximately 50,000 patients will die as a result of their cancer, according to the American Cancer Society. Sales predictions by Market Data Forecast predict that the market for the global pharmaceutical treatment of pancreatic cancer will increase to $3.7 billion by 2027. Â CompetitionÂ The drug discovery and development industry is verycompetitive, characterized by rapid advancements in technology, where protection of proprietary advancements is essential. Any productcandidates that we may successfully develop and commercialize, may compete with existing therapies, or new therapies that may become availablein the future. Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products thatare more effective, have fewer side effects, are more convenient or are less expensive than any products that we may develop.Â We believe our approach to the treatment of Alzheimerâ€™sdisease and other CNS diseases differs from our competitors. Our platform may offer a disease-modifying approach in neurodegenerativeand neurodevelopmental diseases by activation of SIGMAR1. In our preclinical studies, when activated by SIGMAR1 agonists, such as ANAVEXÂ®2-73,SIGMAR1 demonstrated reduced cellular stress before and after RNA gene transcription. Our studies confirm the potential existence of apredictive biomarker of response established through SIGMAR1 mRNA expression that could be used in future clinical trials. Because ofits role in maintaining neuronal homeostasis, we believe sigma receptors show significant promise as viable targets for therapeutic moleculesin an effort to treat Alzheimerâ€™s disease and other CNS diseases and disorders, including Parkinsonâ€™s disease and Rett syndrome,by restoring healthy gene expression.Â 18 Â Â At this time, our competitors are primarily otherbiomedical development companies that are aiming to discover and develop compounds to be used in the treatment of Alzheimerâ€™s diseaseand other CNS diseases, and those companies already doing so. We also face competition from academic institutions and government agencies,both in the United States and abroad.Â Our competitors may have significantly greater financialresources, an established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing,may be in the process of obtaining regulatory approvals and marketing of approved products. These competitors also compete with us inrecruiting and retaining qualified scientific and technical personnel, establishing clinical trial sites and patient registration forclinical trials, as well as in acquiring or developing technologies complementary to, or necessary for, our programs. Smaller or early-stagecompanies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.Â For additional discussion of the risks related tocompetition, see Item 1A â€œRisk Factors.â€Â Patents, Trademarks and Intellectual PropertyÂ We hold ownership or exclusive rights to twenty-five(25) U.S. patents, twenty-five (25) 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.Â We own one issued U.S. patent entitled â€œANAVEXÂ®2-73and certain anticholinesterase inhibitors composition and method for neuroprotection,â€ which claims a composition of matter of ANAVEXÂ®2-73directed to a novel and synergistic neuroprotective compound combined with donepezil and other cholinesterase inhibitors. This patentis expected to expire in June 2034, absent any patent term extension for regulatory delays.Â We own one issued U.S. patent entitled â€œA2-73crystalline polymorph compositions of matter and methods of use thereofâ€. It claims crystals of A2-73 freebase or its fumarate salt,dosage forms and pharmaceutical formulations. This patent is expected to expire in July 2039, absent any patent term extension for regulatorydelays.Â We own four issued U.S. patents each with claims directedto crystalline forms of ANAVEXÂ®2-73. The first of these four patents claims crystalline forms of ANAVEXÂ®2-73,dosage forms and compositions containing crystalline ANAVEXÂ®2-73, and methods of treatment for Alzheimerâ€™s diseaseusing them. This patent is expected to expire in July 2036, absent any patent term extension for regulatory delays. The second of thesefour patents claims pharmaceutical compositions containing a crystalline form of ANAVEXÂ®2-73, and methods of treatmentfor Alzheimerâ€™s disease using the compositions. This patent is expected to expire in June 2036, absent any patent term extensionfor regulatory delays. The third of these four patents claims pharmaceutical compositions containing a crystalline form of ANAVEXÂ®2-73,and methods of treatment for Alzheimerâ€™s disease using the compositions. This patent is expected to expire in June 2036, absentany patent term extension for regulatory delays. The fourth of these four patents claims method of making certain crystalline forms ANAVEXÂ®2-73.This patent is expected to expire in October 2036, absent any patent term extension for regulatory delays.Â We also own three issued U.S. patents for seizuretreatment. The first of these three patents claims methods and dosage forms for treating seizures, the dosage forms containing a low-doseanti-epilepsy drug combined with either: (i) ANAVEXÂ®2-73 and its active metabolite ANAVEXÂ®19-144; or (ii)ANAVEXÂ®19-144. The second of these three patents further claims a combination seizure treatment involving administrationof an anti-epilepsy drug combined with (i) ANAVEXÂ®19-144, or (ii) ANAVEXÂ®19-144 and ANAVEXÂ®2-73.The third of these three patents claims a dosage form for seizure reduction, comprising (i)

ANAVEXÂ®19-144, (ii) ANAVEXÂ®2-73,or (iii) a combination of ANAVEXÂ®19-144 and ANAVEXÂ®2-73; and optionally further comprising a low-dose anti-epilepsydrug. All three patents are expected to expire in October 2035, absent any patent term extension for regulatory delays.Â 19 Â Â We also own four issued U.S. patents with claims directedto treating neurodevelopmental disorders. These patents claim methods for treating a neurodevelopmental disorder, multiple sclerosis,their related biochemical and functional abnormalities, or loss-of-function associated with a neurodevelopmental disorder, by administeringANAVEXÂ®2-73, ANAVEXÂ®19-144, and/or ANAVEXÂ®1-41 (another sigma receptor ligand similar toANAVEXÂ®2-73), or compositions thereof. All four patents are expected to expire in January 2037, absent any patent termextension for regulatory delays.Â In addition, we own one issued U.S. patent with claimsdirected to methods of treating melanoma with a compound related to ANAVEXÂ®2-73. This patent is expected to expire in February2030, absent any patent term extension for regulatory delays.Â We also own an issued U.S. patent that claims crystallineforms of ANAVEXÂ®19-144, dosage forms and compositions containing the crystalline forms of ANAVEXÂ®19-144,and methods of treatment for Alzheimerâ€™s disease. This patent is expected to expire in July 2036, absent any patent term extensionfor regulatory delays.Â Further, we own one issued U.S. patent with claimsdirected to methods of treating cardiac dysfunction with ANAVEXÂ®2-73. This patent is expected to expire in July 2038, absentany patent term extension for regulatory delays. Additionally, we own two issued U.S. patent for the treatment of insomnia, anxiety, oragitation. The first of the two patents claims methods of treating insomnia or anxiety with ANAVEXÂ®2-73, ANAVEXÂ®19-144,and/or ANAVEXÂ®1-41. This patent is expected to expire in September 2038. The second of the two patents claims a dosageform comprising any of, or any combination of ANAVEXÂ®2-73, ANAVEXÂ®19-144, and/or ANAVEXÂ®1-41.This patent is expected to expire in July 2038, absent any patent term extension for regulatory delays.Â Further, we own one issued U.S. patent with claimsdirected to a method of treating systolic hypertension using ANAVEXÂ®2-73. This patent is expected to expire in July 2039,absent any patent term extension for regulatory delays. Additionally, we own one issued U.S. patent with claims directed to pharmaceuticaldosage forms of (-) enantiomer of ANAVEXÂ®2-73. This patent is expected to expire in July 2036, absent any patent term extensionfor regulatory delays.Â We also own three (3) issued U.S. patents relatedto ANAVEXÂ®1066. The first of these three patents claims methods for treating or preventing pain using (+) ANAVEXÂ®1066isomer. The second patent claims methods for treating or preventing pain using (-) ANAVEXÂ®1066 isomer. The third patentclaims dosage forms and pharmaceutical compositions comprising (+) ANAVEXÂ®1066 isomer. All three patents are expected toexpire in November 2036, absent any patent term extension for regulatory delays.Â For ANAVEXÂ®2-73, ANAVEXÂ®19-144,ANAVEXÂ®1-41, and ANAVEXÂ®1066, we also have granted or pending applications in Australia, Canada, China,Europe, Japan, and Hong Kong, which are expected to expire after 2035.Â With regard to ANAVEXÂ®3-71, we ownexclusive rights to two issued U.S. patents with claims respectively directed to the ANAVEXÂ®3-71 compound and methods oftreating various diseases including Alzheimerâ€™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 applicationsthat are granted or pending in Australia, Canada, China, Europe, Japan, Korea, New Zealand, Russia, and South Africa, which are expectedto expire in January 2030.Â We also own other patent applications and certaingranted foreign patents directed to enantiomers, crystals, formulations, uses, and patient selection methods that may provide additionalprotection for one or more of our product candidates.Â We regard patents and other intellectual propertyrights as corporate assets. Accordingly, we attempt to optimize the value of intellectual property in developing our business strategyincluding the selective development, protection, and exploitation of our intellectual property rights. In addition to filings made withintellectual property authorities, we protect our intellectual property and confidential information by means of carefully consideredprocesses of communication and the sharing of information, and by the use of confidentiality and non-disclosure agreements and provisionsfor the same in contractorâ€™s agreements. While no agreement offers absolute protection, such agreements provide some form of recoursein the event of disclosure, or anticipated disclosure.Â 20 Â Â Ourintellectual property position, like that of many biomedical companies, is uncertain and involves complex legal and technical questionsfor which important legal principles are unresolved. For more information regarding challenges to our existing or future patents, seeâ€œRisk Factorsâ€ in Part I, Item 1A of this Annual Report on Form 10-K.Â Government regulationÂ Government authorities in the United States, at thefederal, state and local levels, 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 andimport of products such as those we are developing. A new drug must be approved by the FDA through the NDA or ANDA process before it maybe legally marketed in the United States. We are subject to various government regulations in connection with the development of our pipeline.Â U.S. Drug Development and Regulation Â In the United States, the FDA regulates drugs underthe Federal Food, Drug, and Cosmetic Act and its implementing regulations (â€œFDCAâ€). The process of obtaining regulatory approvalsand the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantialtime and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process,approval process or post approval may subject an applicant to administrative or judicial sanctions. These sanctions could include theFDAâ€™s refusal to approve pending applications, withdrawal of an approval, import refusal, a clinical hold, warning letters, productrecalls, 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 effecton us.Â Once a drug candidate is identified for development,it enters the preclinical testing stage and an Investigational New Drug Application (â€œINDâ€) may be opened for the regulatorydevelopment of the product. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well asother preclinical studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information andanalytical data, to the FDA as part of the IND to conduct clinical trials. The sponsor must also include a protocol detailing, among otherthings, the objectives of the clinical trials, the parameters to be used in monitoring the safety of the trial, and the effectivenesscriteria to be evaluated should the trial include an efficacy evaluation. Some preclinical testing may continue even after the IND isfiled. The IND automatically becomes effective thirty (30) days after receipt by the FDA, unless the 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 trialsdue to safety concerns about ongoing or proposed clinical trials or non-compliance with specific FDA requirements, and the trials maynot begin or continue until the FDA notifies the sponsor that the hold has been lifted.Â All clinical trials must be conducted under the supervisionof one or more qualified investigators in accordance with FDA good clinical practice (â€œGCPâ€) requirements, which include arequirement that all research subjects provide their informed consent in writing for their

participation in any clinical trial. Clinicaltrials must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection inclusion and exclusioncriteria and the safety and/or effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND,and timely safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. An InstitutionalReview Board (â€œIRBâ€) at each institution participating in the clinical trial must review and approve each protocol beforea clinical trial may commence at the institution and must also approve the information regarding the trial as well as the informed consentform that must be provided to each trial participant or his or her legal representative, monitor the study until completed and otherwisecomply with all applicable IRB regulations.Â Human clinical trials are typically conducted in threesequential phases that may overlap or be combined in certain cases:Â 21 Â Â Phase 1: The compound is initially introduced intohealthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, togain 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 theproduct may be too toxic to ethically administer to healthy volunteers, the initial human testing may be conducted on patients with thetarget disease or condition. Sponsors sometimes subdivide their Phase 1 clinical trials into Phase 1a and Phase 1b clinical trials. Phase1b clinical trials are typically aimed at confirming dosage, PK and safety in a larger number of patients. Some Phase 1b clinical trialsevaluate biomarkers or surrogate markers that may be associated with efficacy in patients with specific types of diseases or conditions.Â Phase 2: This phase involves clinical trials in alimited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the productfor specific targeted diseases or conditions and to confirm dosage tolerance and appropriate dosage.Â Phase 3: Phase 3 clinical trials are undertaken tofurther evaluate dosage, clinical efficacy and safety in an expanded patient population, generally at geographically dispersed clinicaltrial sites. These clinical trials, often referred to as â€œpivotalâ€ or â€œconfirmatoryâ€ clinical trials, are intendedto establish the overall risk-benefit ratio of the compound and provide, if appropriate, an adequate basis for product approval and labeling.Â The FDA or the sponsor may suspend a clinical trialat any time on various grounds, including any finding that the research subjects or patients are being exposed to an unacceptable healthrisk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conductedin accordance with the IRBâ€™s requirements or if the drug has been associated with unexpected, serious harm to study subjects. Inaddition, clinical trials may be overseen by an independent group of qualified experts organized by the sponsor, known as a data safetymonitoring board or committee. Depending on its charter, this board or committee may determine whether a trial may move forward at designatedcheck points based on access to certain data from the trial.Â Phase 4: Phase 4 or post-approval trials may alsobe conducted after a drug receives initial marketing approval. These trials, often referred to as â€œPhase 4â€ trials, are usedto gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA maymandate the performance of such clinical trials as a condition of approval of continued marketing of the product.Â During the development of a new drug, sponsors aregiven several opportunities to meet with the FDA. These meetings can provide an opportunity for the sponsor to share information aboutthe progress of the application or clinical trials, for the FDA to provide advice, and for the sponsor and the FDA to reach agreementon the next phase of development. These meetings may occur prior to the submission of an IND, at the end of Phase 2 clinical trials, orbefore an NDA is ultimately submitted. Sponsors typically use the meetings at the end of the Phase 2 trials to discuss Phase 2 clinicalresults and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug. Meetings atother times may be made upon request and are subject to approval by the FDA.Â Concurrent with clinical trials, companies typicallycomplete additional, animal or other non-clinical studies, develop additional information about the chemistry and physicochemical characteristicsof the drug, and finalize a process for manufacturing the product in commercial quantities in accordance with the FDAâ€™s currentGood Manufacturing Practices (â€œcGMPâ€) requirements. The manufacturing process must consistently produce quality batches ofthe drug and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of thefinal drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate theeffectiveness of the packaging and that the compound does not undergo unacceptable deterioration over its shelf life.Â While the IND is active, progress reports summarizingthe results of ongoing clinical trials and nonclinical studies performed since the last progress report must be submitted on at leastan annual basis to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected adverseevents, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animalor in vitro testing suggesting a significant risk to humans, and any clinically important, increased incidence of a serious adverse reactioncompared to that listed in the protocol or investigator brochure.Â 22 Â Â There are also requirements governing the submissionof certain clinical trials and completed trial results to public registries. Sponsors of certain clinical trials of FDA-regulated productsare required to register and disclose specified clinical trial registration and results information, which is made publicly availableat www.clinicaltrials.gov. Failure to properly report clinical trial results can result in civil monetary penalties. Disclosure of clinicaltrial results can often be delayed until the new product or new indication being studied has been approved.Â U.S. review and approval process Â The results of product development, preclinical andother non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on thechemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of a New Drug Application (â€œNDAâ€).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.Â The 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 assureand preserve the productâ€™s identity, strength, quality and purity. Under the Prescription Drug User Fee Act (â€œPDUFAâ€),the FDA has a goal of ten months from the date of â€œfilingâ€ of a standard, completed NDA for a new molecular entity to reviewand act on the submission. This review typically takes twelve months from the date the NDA is submitted to the FDA because the FDA hasapproximately two months to make a â€œfilingâ€ decision after the application is submitted. The FDA conducts a preliminary reviewof all NDAs within the first sixty days after submission, before accepting them for filing, to determine whether they are sufficientlycomplete to permit substantive review. The 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 acceptsit for filing.Â The FDA may refer an application for a new drug toan advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, thatreviews, evaluates and provides a recommendation as to whether and under what

conditions the application should be approved. The FDA isnot bound by the recommendations of such an advisory committee, but it considers advisory committee recommendations carefully when makingdecisions.Â Before approving an NDA, the FDA will also inspectthe facility where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processesand facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within requiredspecifications. Before approving an NDA, the FDA may also inspect one or more clinical trial sites to assure compliance with GCP requirementsand inspect the clinical trial records.Â After the FDA evaluates an NDA, it will issue an approvalletter or a Complete Response Letter. A Complete Response Letter indicates that the review cycle of the application is complete, and theapplication will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDAidentified by the FDA and may require additional clinical data, such as an additional pivotal Phase 3 trial or other significant and time-consumingrequirements related to clinical trials, nonclinical studies or product manufacturing. If a Complete Response Letter is issued, the sponsormust resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data andinformation are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval. An approval letter authorizes commercialmarketing of the drug with prescribing information for specific indications.Â The Pediatric Research Equity Act (â€œPREAâ€),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 unlessthe sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for theclaimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation forwhich the product is safe and effective. The sponsor or the FDA may request a deferral of pediatric clinical trials for some or all ofthe pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval foruse in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected beforethe pediatric clinical trials begin. The 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.Â 23 Â Â If a drug receives FDA approval, the approval maybe limited to specific diseases and dosages, which could restrict the commercial value of the product. In addition, the FDA may requiretesting and surveillance programs to monitor the safety of approved products which have been commercialized and may require a sponsorto conduct post-marketing clinical trials (Phase 4 clinical trials), which are designed to further assess a drugâ€™s safety and effectivenessafter NDA approval. The FDA may also place other conditions on approval, including a requirement for a risk evaluation and mitigationstrategy (â€œREMSâ€) to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submita proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physiciancommunication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimizationtools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescribing or dispensingof products. Marketing approval may be withdrawn for non-compliance with REMS or other regulatory requirements, or if problems occur followinginitial marketing.Â Post-approval requirements Â Once an approval is granted, the FDA may withdrawthe approval if compliance with regulatory standards is not maintained or if problems occur after the drug reaches the market. Later discoveryof 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 additionallabeling claims, are subject to further FDA review and approval. Manufacturers and other entities involved in the manufacture and distributionof approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannouncedinspections by the FDA and certain state agencies for compliance with cGMP regulations and other laws and regulations.Â Any drug product manufactured or distributed by uspursuant to FDA approval will be subject to continuing regulation by the FDA, including, among other things, record-keeping requirements,reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, drug sampling and distributionrequirements, 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 themarket, and imposes requirements and restrictions on drug manufacturers, such as those related to direct-to-consumer advertising, theprohibition on promoting products for uses or in patient populations that are not described in the productâ€™s approved labeling (knownas â€œoff-label useâ€), 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 restrictionson the marketing of a product for a certain indication or withdrawal of the product from the market as well as possible civil or criminalsanctions. Failure to comply with the applicable governmental requirements at any time during the product development process, approvalprocess or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adversepublicity. The FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical holds on post-marketingclinical trials, enforcement letters, import refusals, product recalls, product seizures, total or partial suspension of production ordistribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment,restitution, disgorgement of profits, or civil or criminal penalties.Â Expedited development and review programs Â The FDA has a fast track designation program thatis intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugsare eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstratethe potential to address unmet medical needs for the disease or condition. With regard to a fast track product, the FDA may consider forreview sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for thesubmission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, andthe sponsor pays any required user fees upon submission of the first section of the NDA.Â 24 Â Â Any product submitted to the FDA for approval, includinga 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.Â A product is eligible for priority review if it isintended to treat a serious condition, and if approved, would provide a significant improvement in safety or efficacy compared to currentlymarketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated forpriority review in an effort to facilitate the review. The

FDA endeavors to review applications with priority review designations withinsix months of the filing date, as compared to ten months for review of NDAs under its current PDUFA review goals.Â In addition, a product may be eligible for acceleratedapproval. Drugs intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determinationthat the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on a clinical endpointthat can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversiblemorbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availabilityor lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approvalperform adequate and well-controlled post-marketing clinical trials. Drugs receiving accelerated approval may be subject to expeditedwithdrawal procedures if the sponsor fails to conduct the required post-marketing trials or if such trials fail to verify the predictedclinical 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.Â The Food and Drug Administration Safety and InnovationAct (â€œFDASIAâ€) established a category of drugs referred to as â€œbreakthrough therapiesâ€ that may be eligible toreceive breakthrough therapy designation. A sponsor may seek FDA designation of a compound as a â€œbreakthrough therapyâ€ ifthe product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or conditionand preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one ormore clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includesall of the fast track program features, as well as more intensive FDA interaction and guidance. The breakthrough therapy designation isa distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteriaare met. If a product is designated as breakthrough therapy, the FDA will work to expedite the development and review of such drug.Â Fast track designation, priority review and breakthroughtherapy designation do not change the standards for approval but may expedite the development or approval process. However, even if aproduct qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualificationor decide that the time period for FDA review or approval will not be shortened.Â Orphan drug designation Â Under the Orphan Drug Act, the FDA may grant orphandesignation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individualsin the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that thecost of developing and making a drug product available in the United States for this type of disease or condition will be recovered fromsales of the product. Orphan designation must be requested before an NDA is submitted. After the FDA grants orphan designation, the identityof the therapeutic agent and its potential orphan use are publicly disclosed by the FDA. Orphan designation does not convey any advantagein or shorten the duration of the regulatory review and approval process.Â 25 Â Â If a product that has orphan designation subsequentlyreceives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan productexclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for sevenyears, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inabilityto manufacture the product in sufficient quantities. The designation of such drug also entitles a party to financial incentives such asopportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. However, competitors may receive approvalof different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but fora different indication for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of one of our compoundsfor seven years if our compound is determined to be contained within the competitorâ€™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 marketingapproval for an indication broader than what is designated, it may not be entitled to orphan exclusivity.Â Abbreviated New Drug Applications, 505(b)(2) Applications,and Marketing exclusivity Â In seeking approval for a drug through an NDA, applicantsare required to list with the FDA each patent with claims that cover the applicantâ€™s drug or an approved method of use of the drug.Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDAâ€™s Approved DrugProducts with Therapeutic Equivalence Evaluations, commonly known as the â€œOrange Book.â€ Drugs listed in the Orange Book can,in turn, be cited by competitors in support of approval of an Abbreviated New Drug Application, or ANDA, or a 505(b)(2)Â application.In this case, the original NDA (theÂ so-calledÂ pioneer drug) is known as the â€œlistedâ€ drug or â€œreference-listedâ€drug. An ANDA provides for marketing of a drug that has the same active ingredient and the same strength, route of administration anddosage form as the listed drug and has been shown through testing to be bioequivalent to the listed drug or receives a waiver from bioequivalencetesting. ANDA applicants are generally not required to conduct or submit results of preclinical or clinical tests to prove the safetyor effectiveness of their drug, other than the requirement for bioequivalence testing. Drugs approved in this way are considered therapeuticallyequivalent, and are commonly referred to as â€œgeneric equivalentsâ€ to the listed drug. These drugs then generally can be substitutedby pharmacists under prescriptions written for the original listed drug.Â A 505(b)(2) application is a type of NDA that relies,in part, upon data the applicant does not own and to which it does not have a right of reference. Such applications often are submittedfor changes to previously approved drug products, and rely on the FDAâ€™s prior findings of safety and effectiveness for a third partyâ€™sNDA to abbreviate the showings the sponsor of the 505(b)(2) application must make to establish that its product is safe and effective.Â The ANDA or 505(b)(2)Â applicant is required tocertify to the FDA concerning any patents listed for the referenced approved drug in FDAâ€™s Orange Book. Specifically, for each listedpatent, the applicant must certify that: (1)Â the required patent information has not been filed; (2)Â the listed patent has expired;(3)Â the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (4)Â thelisted patent is invalid, unenforceable or will not be infringed by the new drug. A certification that the new drug will not infringethe already approved drugâ€™s listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification.If the ANDA or 505(b)(2)Â applicant does not include a Paragraph IV certification, the ANDA or 505(b)(2)Â application will notbe approved until all of the listed patents claiming the referenced drug have expired, except for any listed patents that only apply touses of the drug not being sought by the ANDA or 505(b)(2)Â applicant.Â If the ANDA or 505(b)(2)Â applicant has made aParagraph IV certification, the applicant must also send notice of a Paragraph IV Notice Letter to the NDA and patent holders once theANDA or 505(b)(2)Â application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringementlawsuit in response to the notice of the Paragraph IV Notice Letter. The filing of a patent infringement lawsuit within 45Â days ofthe receipt of notice of a

Paragraph IV Notice Letter automatically prevents the FDA from approving the ANDA until the earlier of 30Â months,expiration of the patent, settlement of the lawsuit, modification by a court or a decision in the infringement case that is favorableto the ANDA or 505(b)(2)Â applicant. As discussed below, the ANDA or 505(b)(2)Â application also will not be approved until anyapplicableÂ non-patentÂ exclusivity listed in the Orange Book for the reference-listed drug has expired.Â 26 Â Â Market exclusivity provisions under the FDCA can delaythe submission or approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivitywithin the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entityif the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsiblefor the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviatednew drug application (â€œANDAâ€), or an NDA submitted under Section 505(b)(2) (a â€œ505(b)(2) NDAâ€), submitted by anothercompany for another drug containing the same active moiety, regardless of whether the drug is intended for the same indication as theoriginal innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the datarequired for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity ornon-infringement to one of the patents listed with the FDA by the innovator NDA holder.Â The FDCA alternatively provides three years of marketingexclusivity for an NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that wereconducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, as, for example, newindications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug receivedapproval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugscontaining the active ingredient for the original indication or condition of use. Five-year and three-year exclusivity will not delaythe submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right ofreference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.Â Pediatric exclusivity is another type of marketingexclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attachedto another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. Theissuance 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.Â United States Patent Term RestorationÂ Depending upon the timing, duration and specificsof FDA approval of our future product candidates, some of our United States patents may be eligible for limited patent term extensionunder the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-WaxmanAmendments permit restoration of the patent term of up to five years as compensation for patent term lost during the FDA regulatory reviewprocess for a drug that has not been previously approved for commercial marketing. Patent-term restoration, however, cannot extend theremaining term of a patent beyond a total of 14 years from the productâ€™s approval date and only those claims covering such approveddrug product, a method for using it or a method for manufacturing it may be extended. The patent-term restoration period is generallyÂ one-halfÂ thetime between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and theapproval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence.Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted priorto the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the applicationfor any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensedpatents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factorsinvolved in the filing of the relevant NDA.Â Foreign SalesÂ Sales outside the United States of potential drugcompounds 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 requiressignificant resources. In most cases, if the FDA has not approved a potential drug compound for sale in the United States, the potentialdrug compound may be exported for sale outside of the United States, only if it has been approved in any one of the following: the EuropeanUnion or a country in the European Economic Area (the countries in the European Union and the European Free Trade Association) if thedrug or device is marketed in that country or the drug or device is authorized for general marketing in the European Economic Area, Canada,Australia, New Zealand, Japan, Israel, Switzerland and South Africa. There are specific FDA regulations that govern this process.Â 27 Â Â U.S. coverage and reimbursement Â Significant uncertainty exists as to the coverageand reimbursement status of any compound for which we may seek regulatory approval. Sales in the United States will depend in part onthe availability of sufficient coverage and adequate reimbursement from third-party payors, which include government health programs suchas 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 denialby payors.Â The process for determining whether a payor will providecoverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product.A payorâ€™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 Medicarecoverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods andapproval processes. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. If coverage and adequatereimbursement are not available, or are available only at limited levels, successful commercialization of, and obtaining a satisfactoryfinancial return on, any product we develop may not be possible.Â Third-party payors are increasingly challenging theprice 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 studiesin order to demonstrate the medical necessity and cost-effectiveness of any products, which would be in addition to the costs expendedto obtain regulatory approvals. Third-party payors may not consider our compounds to be medically necessary or cost-effective comparedto other available therapies, or the rebate percentages required to secure favorable coverage may not yield an adequate margin over costor may not enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development. Additionally,we or our collaborators may develop companion diagnostic tests for use with our product candidates. Companion diagnostic tests requirecoverage

and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products.Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companiondiagnostics.Â Fraud and Abuse Laws Â Federal and state health care laws and regulationsrestrict business practices in the biopharmaceutical industry. In the biopharmaceutical industry, there are a number of federal and statehealth 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 statementlaw, civil monetary penalty laws, exclusion law, and other civil, criminal, and administrative laws. Health care laws, regulations, andguidance continuously evolve and are thereby subject to constant change.Â The Federal Anti-Kickback Statute, 42 U.S.C. Â§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 forthe:Â Â â— Â 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 Â â— Â 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. Â There are a number of narrow safe harbors to the FederalAnti-Kickback Statute. Such safe harbors permit certain payments and business practices that, although they would otherwise potentiallyimplicate the Federal Anti-Kickback Statute, are not treated as an offense under the same if all of the requirements of the specific applicablesafe harbor are met. Actual knowledge of the statute or specific intent to violate it is not required in order for a person or entityto have committed a violation.Â 28 Â Â The Federal Anti-Kickback Statute applies to certainarrangements with healthcare providers, product end users and other parties, including marketing arrangements and discounts and otherfinancial 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-KickbackStatute 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 inthe need to curtail and/or restructure operations. Any penalties, damages, fines, exclusions, curtailment or restructuring of operationscould adversely affect the ability to operate a business, financial condition, and results of operations. A violation of the Federal Anti-KickbackStatute can serve as a false or fraudulent claim for purposes of the civil False Claims Act and the civil monetary penalties statute.Â The federal Health Insurance Portability and AccountabilityAct of 1996 (â€œHIPAAâ€) among other things, enacted numerous provisions that prohibit knowingly and willfully executing, orattempting to execute, a scheme or artifice to defraud any healthcare benefit program or 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 healthcare benefit program,regardless of the payor (e.g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowinglyand willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitiousor fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcarematters. These provisions include 18 U.S.C. Â§Â§ 286, 287, 669, 1035, 1347, and 1518, all as described further below.Â The Ethics in Patient Referrals Act, commonly knownas the â€œStark Law,â€ 42 U.S.C. Â§ 1395nn, prohibits a physician from making referrals for certain â€œdesignated healthservicesâ€ payable by Medicare to an entity in which the physician or an immediate family member of such physician has an ownershipor 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 wouldotherwise potentially implicate the Stark Law, are not treated as a violation under the same if the requirements of the specific exceptionsare 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 therecan be no guarantee that regulatory authorities will not determine or assert that arrangements are in violation of the Stark Law and donot otherwise meet applicable Stark Law exceptions.Â The federal false statements statute, 42 U.S.C. Â§1320a-7b(a), prohibits knowingly and willfully falsifying, concealing, or omitting a material fact or making any materially false statementin connection with the delivery of health care benefits, items, or services. Similarly, 18 U.S.C. Â§ 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 orusing any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement orentry. In addition to criminal penalties, violation of these statutes may result in collateral administrative sanctions, including exclusionfrom participation in Medicare, Medicaid and other federal health care programs.Â 18 U.S.C. Â§ 669 prohibits knowingly and willfullyembezzling, stealing, or otherwise without authority converting to the use of any person or entity other than the rightful owner, or intentionallymisapplying any of the moneys, funds, securities, premiums, credits, property, or other assets of a health care benefit program. In additionto criminal penalties, violation of this statute may result in collateral administrative sanctions, including exclusion from participationin Medicare, Medicaid and other federal health care programs.Â The criminal health care fraud statute, 18 U.S.C.Â§ 1347, establishes criminal liability for whoever knowingly and willfully executes, or attempts to execute, a scheme or artificeto defraud any health care benefit program, or to obtain, by means of false or fraudulent pretenses, representations, or promises, anyof the money or property owned by, or under the custody or control of, any health care benefit program, in connection with the deliveryof or payment for health care benefits, items, or services. In addition to criminal penalties, violation of this statute may result incollateral 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.Â 29 Â Â 18 U.S.C. Â§ 1518 establishes criminal liabilityfor whoever willfully prevents, obstructs, misleads, delays or attempts to prevent, obstruct, mislead, or delay the communication of informationor records relating to a violation of a Federal health care offense to a criminal investigator. In addition to criminal penalties, violationof this statute may result in collateral administrative sanctions, including exclusion from participation in Medicare, Medicaid and otherfederal health care programs.Â 18 U.S.C. Â§ 286 establishes criminal liabilityfor whoever enters into any agreement, combination, or conspiracy to defraud the United States, or any department or agency thereof, byobtaining 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, Medicaidand other federal health care programs.Â 18 U.S.C. Â§ 287 establishes criminal liabilityfor whoever knowingly makes or presents a false, fictitious or fraudulent claim to the United States Government, including any departmentor agency thereof. In addition to criminal penalties, violation of this statute may result in collateral administrative sanctions, includingexclusion from participation in Medicare, Medicaid and other federal health care programs.Â The Federal False Claims Act, 31 U.S.C. Â§ 3729,et seq., provides, in part, that the federal governmentâ€”or a private party on behalf of the governmentâ€”may bring a lawsuitagainst any person whom it believes has knowingly presented, or caused to be presented, a false or fraudulent claim for payment, or whohas 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 thefederal 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 forprivate parties to bring whistleblower lawsuits against companies.Â The civil monetary penalties law, 42 U.S.C. Â§1320a-7a, provides, in part, that the federal government may seek civil monetary penalties against any person who presents or causes tobe presented claims to a Federal health care program that the person knows or should know is for an item or services that was not providedas 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 federalgovernment may also seek civil monetary penalties for a wide variety of other conduct, including offering remuneration to influence aMedicare or Medicaid beneficiaryâ€™s selection of providers and violations of the Federal Anti-Kickback Statute.Â Violations of the Federal False Claims Act and/orthe Civil Monetary Penalties Law can result in penalties ranging from $12,537 to $25,076 for each false claim violation of the FederalFalse Claims Act and varying amounts based on the type of violation of the Civil Monetary Penalties Law, plus up to three times the amountof damages that the federal government sustained. In addition, the federal government may also seek exclusion from participation in allfederal health care programs.Â 42 U.S.C. Section 1320a-7 provides that individualsand entities can be mandatorily or permissively excluded from participation in federal health care programs. The grounds for mandatoryexclusion include, but are not limited to, conviction for a criminal offense related to the delivery of an item or service reimbursedunder 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 aninvestigation or audit, and/or failure to disclose certain required information. Exclusion from federal health care programsâ€”whethermandatory or permissiveâ€”may mean that our customers may not be able to get reimbursed by federal and/or state health care programsfor use or dispensing of our products.Â State Fraud and Abuse ProvisionsÂ Many states have also adopted some form of anti-kickbackand anti-referral laws and false claims acts and civil monetary penalties and other fraud and abuse provisions that apply regardless ofpayer, in addition to items and services reimbursed under Medicaid and other state programs. A determination of liability under such lawscould result in fines, penalties, and exclusion, as well as restrictions on the ability to operate in these jurisdictions.Â 30 Â Â Corporate liability can be present as a result ofthe illegal activities of employees, representatives, contractors, collaborators, agents, subsidiaries, or affiliates, even if they werenot explicitly authorized. There can be no assurance that all employees, representatives, contractors, collaborators, agents, subsidiariesor affiliates will comply with the foregoing laws at all times. Violation of the aforementioned and other laws could result in whistleblowercomplaints, investigations, sanctions, settlements, prosecution, government oversight and reporting, other enforcement actions, disgorgementof profits, significant fines, damages, other civil and criminal penalties or injunctions or other administrative remedies, suspensionand/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 representativeswho 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 ina materially significant diversion of managementâ€™s attention and resources and significant defense costs and other professionalfees. Enforcement actions and sanctions could further harm business, financial condition, and results of operations. Any of the consequencescontained in this paragraph and section could adversely affect the ability to operate the business, financial condition, and the resultsof operations.Â Sunshine ActÂ The Sunshine Act requires manufacturers of productsreimbursed by Medicare, Medicaid or the Childrenâ€™s Health Insurance Program (â€œCHIPâ€) to collect and annually reportdetailed data to the Centers for Medicare and Medicaid Services (â€œCMSâ€) regarding payments or other transfers of value tophysicians, certain other health care providers (such as physicians assistants and nurse practitioners) and teaching hospitals (â€œcoveredrecipientsâ€), as well as any ownership or investment interest held by physicians and their immediate family members. The reportingdata must be accompanied by an attestation as to the accuracy of the data and failure to timely and accurately submit required informationmay result in civil monetary penalties.Â Health Insurance Portability and AccountabilityAct Â Besides enacting the program integrity provisionsdescribed above, HIPAA, also created a new set of privacy and security requirements. As amended by the Health Information Technology forEconomic and Clinical Health Act, and implementing regulations thereunder, HIPAA requires certain healthcare providers, health plans andhealthcare clearinghouses who conduct specified electronic healthcare transactions (â€œcovered entitiesâ€), as well as theirindependent contractors and agents who conduct certain activities involving protected health information on their behalf (â€œbusinessassociatesâ€) 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 otherchanges, HITECH made HIPAA security standards directly applicable to business associates, increased the tiered civil and criminal finesand penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys generalnew authority to file actions to enforce HIPAA. Further, the breach notification rule implemented under HITECH requires covered entitiesto notify affected individuals, the U.S. Department of Health and Human Services Office of Civil Rights (â€œOCRâ€), the agencythat 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.Â Legislative Activities Aimed at Controlling DrugCosts Â In the United States, there have been, and continueto be proposed and enacted legislation at the federal and state levels designed to, among other things, bring more transparency to drugpricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reformgovernment program reimbursement methodologies for drugs. For example, in July 2021, the Biden administration released an

executive order,â€œPromoting Competition in the American Economy,â€ with multiple provisions aimed at prescription drugs. In response to Bidenâ€™sexecutive order, on September 9, 2021, the U.S. Department of Health and Human Services (â€œHHSâ€) released a Comprehensive Planfor Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policiesthat Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition,Â 31 Â Â the InflationReduction Act (â€œIRAâ€) passed on August 16, 2022. The IRA, among other things, (1) directs HHS to negotiate the price of certainhighly-utilized single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare PartD to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, althoughthey may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impacton the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directingHHS to submit a report within 90 days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new modelsfor lowering drug costs for Medicare and Medicaid beneficiaries. We expect that additional U.S. federal healthcare reform measures willbe adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services,which could result in reduced demand for our product candidates or additional pricing pressures.Â Research and Development ExpensesÂ Historically, a significant portion of our operatingexpenses related to research and development. See our Consolidated Financial Statements contained elsewhere in this Annual Report forcosts and expenses related to research and development, and other financial information for fiscal years 2024 and 2023.Â Scientific Advisors Â We are advised by scientists and physicians with experiencerelevant to our Company and our product candidates. Our scientific advisors include clinicians and scientists who are affiliated witha number of highly regarded medical institutions.Â EmployeesÂ We currently have approximately forty-two full-timeemployees, and we retain several independent contractors on a regular or as-needed basis. We believe that we have good relations withour employees.Â Available InformationÂ Our internet website address is www.anavex.com. OurAnnual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnishedpursuant to section 13(a) or 15(d) of the Exchange Act are available there free of charge. We include our website address in this reportonly 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 incorporatedinto this report.Â ITEM 1A. RISK FACTORSÂ Risk Factor SummaryÂ The following is a summary of the risks and uncertaintiesthat could cause our business, financial condition or operating results to be harmed. We encourage you to carefully review the full riskfactors contained in this report in their entirety for additional information regarding these risks and uncertainties.Â Â·Our history of losses and no revenue raises a risk regarding our ability to continue as a going concernin the future;Â Â·We have a very limited relevant operating history upon which an evaluation of our performance and prospectscan be made. We may never be able to successfully develop marketable products or generate any revenue. If we cannot generate sufficientrevenues, we may suspend or cease operations;Â Â·Our research and development plans will require substantial additional future funding. We may be unableto raise capital when needed, which would force us to delay, reduce or eliminate our research and development activities;Â 32 Â Â Â·We will need additional funding and may be unable to raise additional capital when needed, which wouldforce us to delay, reduce or eliminate our research and development activities;Â Â·Even if our products are approved, we may not be able to generate significant revenues from or successfullycommercialize them, which will adversely affect our financial results and financial condition and we will have to delay or terminate someor all of our research and development plans which may force us to cease operations;Â Â·Our research and development plans require substantial additional future funding which could impact ouroperations and financial condition;Â Â·If we or any companion diagnostic collaborator of ours are unable to timely develop and obtain regulatoryapproval for companion diagnostic tests for our drug candidates, we may not realize the commercial potential of our drug candidates;Â Â·The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy,time-consuming and inherently unpredictable, which could lead to our inability to generate product revenue;Â Â·Regulatory authorities may not accept data from our trials conducted outside the United States;Â Â·Fast Track designation or breakthrough therapy designation that we have received or may seek out may notactually lead to a faster FDA review and approval process;Â Â·We may be unable to maintain any benefits associated with orphan drug designation, including market exclusivity;Â Â·If we fail to demonstrate efficacy in our non-clinical studies and clinical trials our future businessprospects, financial condition and operating results will be materially adversely affected;Â Â·If a particular product candidate causes undesirable side effects, then we may be unable to receive regulatoryapproval of or commercialize such product candidate;Â Â·Wea re highly dependent on our key personnel and if we are not successful in attracting and retaininghighly qualified personnel, we may not be able to successfully implement our business strategy;Â Â·If we do not obtain the support of qualified scientific collaborators, our revenue, growth and profitabilitywill likely be limited, which would have a material adverse effect on our business;Â Â·We may not be able to develop, market or generate sales of our products to the extent anticipated. Ourbusiness may fail and investors could lose all their investment in our Company;Â Â·None of our potential drug compounds may reach the commercial market and our business may fail;Â Â·Material modifications in the methods of product candidate manufacturing may result in additional costsor delay;Â Â·Our technologies and future products may be rendered undesirable or obsolete if our competitors succeedin developing products and technologies faster or that are more effective or with a better profile than our own, or if scientific developmentschange our understanding of the potential scope and utility of our potential products;Â Â·We have advanced our research and development efforts on the treatment of neurodegenerative and centralnervous system, or CNS, disorders, a field that has seen very limited success in product development;Â Â·Our reliance on third parties may result in delays in completing, or a failure to complete, non-clinicaltesting or clinical trials if they fail to perform under our agreements with them or non-compliance with regulations;Â 33 Â Â Â·If we fail to compete with respect to partnering, licensing, mergers, acquisitions, joint venture andother collaboration opportunities, our ability to research and develop our potential drug compounds may be limited;Â Â·The use of any of our products in clinical trials may expose us to liability claims, causing our businessto suffer;Â Â·If we are unable to safeguard against security breaches with respect to our information systems, our businessmay be adversely affected;Â Â·Continuing regulatory obligations and ongoing regulatory review may result in additional expense. Ourcompounds could be subject to restrictions on marketing or withdrawal from the market, and we may be subject to penalties when and ifany of them are approved;Â Â·Changes in funding for the FDA, the SEC and other government agencies could prevent these agencies fromperforming normal functions on which the operations of our business may rely, which could negatively affect our business;Â Â·We receive Australian government research and development income tax incentive refunds. Loss of accessto such incentives could have a negative effect on our future

cash flows and the funding of future research and development projects;Â Â·Operating our business internationally carries various risks which could materially adversely affect ourbusiness;Â Â·Our ability to use our net operating loss carryforwards and tax credit carryforwards may be subject tolimitation;Â Â·Healthcare laws and regulations could expose us to criminal sanctions, civil and administrative penalties,contractual damages, reputational harm and diminished profits and future earnings, among other penalties;Â Â·We expect current and future legislation affecting the pharmaceutical industry, including drug pricingreform, to impact our business generally, which could adversely affect our business operations;Â Â·Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved,could limit our ability to market those products and decrease our ability to generate product revenue;Â Â·Issuing additional shares of common stock will result in the dilution of our existing stockholders andmay cause our stock price to fall. A decline in our stock price could affect our ability to raise further working capital and adverselyaffect our operations. Raising funds at lower prices would severely dilute existing or future investors;Â Â·Our stock price has been volatile and may be volatile in the future and our common stock may become thetarget of a â€œshort squeezeâ€;Â Â·If we fail to maintain an effective system of internal control over financial reporting, we may not beable to accurately report our financial results or prevent fraud. Our disclosure controls and procedures may not prevent or detect allerrors or acts of fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harmour business and the trading price of our common stock;Â Â·Patent terms may be inadequate to protect our competitive position on our product candidates. If we areunable to obtain and maintain sufficient intellectual property protection for our product candidates, our competitors could develop andcommercialize product candidates similar or identical to ours, and our ability to successfully commercialize our product candidates maybe impaired;Â Â·If we fail to comply with our obligations in intellectual property licensing agreements or experiencedisruptions to our business relationships with our licensors, we could lose important intellectual property rights. If we are unable toprotect the confidentiality of our trade secrets, our business would be harmed;Â 34 Â Â Â·Intellectual property infringement claims may adversely affect our development and commercialization efforts;Â Â·We may be subject to claims that our employees, consultants or independent contractors have wrongfullyused or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secretsof their former employers;Â Â·We may become involved in lawsuits to protect or enforce our patents or other intellectual property;Â Obtaining and maintaining our patent protectiondepends on compliance with various requirements imposed by governmental patent agencies. Changes in patent law could impair our abilityto protect our product candidates; andÂ Â·We may fail to protect our intellectual property rights or the confidentiality of our trade secrets. Changesin patent law could diminish the value of our patents and patent applications in general.Â In addition to other information in this Annual Reporton Form 10-K, the following risk factors should be carefully considered in evaluating our business because such factors may have a significantimpact on our business, operating results, liquidity and financial condition. As a result of the risk factors set forth below, actualresults could differ materially from those projected in any forward-looking statements. Additional risks and uncertainties not presentlyknown to us, or that we currently consider to be immaterial, may also impact our business, operating results, liquidity and financialcondition. If any such risks occur, our business, operating results, liquidity and financial condition could be materially affected inan adverse manner. Under such circumstances, the trading price of our securities could decline, and you may lose all or part of your investment.Â Risks Related to our CompanyÂ 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.Â Since inception through September 30, 2024, we haveaccumulated a deficit of approximately $336 million. We can offer no assurance that we will ever operate profitably or that we will generatepositive cash flow in the future. To date, we have not generated any revenues from our operations. Our history of losses and no revenuescreates a greater risk of our continued ability to continue as a going concern in the future. As a result, our management expects thebusiness to continue to experience negative cash flows for the foreseeable future and cannot predict when, if ever, our business mightbecome profitable. We will need to raise additional funds, and such funds may not be available on commercially acceptable terms, if atall. 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 resultsof operations.Â We are an early clinical stage pharmaceuticalresearch and development company and may never be able to successfully develop marketable products or generate any revenue. We have avery limited relevant operating history upon which an evaluation of our performance and prospects can be made. There is no assurance thatour future operations will result in profits. If we cannot generate sufficient revenues, we may suspend or cease operations.Â We are an early clinical stage company and have notgenerated any revenues to date and have no operating history. Moreover, we cannot be certain that our research and development effortswill be successful or, if successful, that our potential drug compounds will ever be approved for sale to pharmaceutical companies orgenerate 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 capitalrequirements, failure of potential drug compounds either in non-clinical testing or in clinical trials, failure to establish businessrelationships and competitive disadvantages against larger and more established companies. If we fail to become profitable, we may suspendor cease operations.Â 35 Â Â We will need additional funding and may be unableto raise additional capital when needed, which would force us to delay, reduce or eliminate our research and development activities.Â To date, we have funded our operations primarily throughprivate placement of our equity securities, through issuances of shares under the Purchase Agreement with Lincoln Park Capital Fund, LLC(â€œLincoln Parkâ€) pursuant to which the Company may direct Lincoln Park to purchase shares of common stock registered underan effective registration statement, or, historically, through draws under our â€œat-the-market offeringâ€ in connection withthe Amended and Restated Sales Agreement with Cantor Fitzgerald & Co. and SVB Leerink LLC (the â€œSales Agentsâ€), pursuantto which we could offer and sell shares of common stock registered under an effective registration statement from time to time throughthe Sales Agents. The Company terminated the Sales Agreement in July 2024. We will need to raise additional funding and the current economicconditions may have a negative impact on our ability to raise additional needed capital on terms that are favorable to our Company orat 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 willbe available on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of, oreliminate one or more of our research and development activities.Â Risks Related to our BusinessÂ Even if we are able to develop our potentialdrug compounds, we may not be able to receive regulatory approval, or if approved, we

may not be able to generate significant revenuesor successfully commercialize our products, which will adversely affect our financial results and financial condition and we will haveto delay or terminate some or all of our research and development plans which may force us to cease operations.Â All of our potential drug compounds are exclusivelyfocused on SIGMAR1 which has not previously been the subject of any approved drug products and will require extensive additional researchand 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 similarregulatory 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 potentialdrug compounds we intend to develop will be approved for marketing. There are many reasons that we may fail in our efforts to developour potential drug compounds. These include:Â Â â—Â the possibility that non-clinical testing or clinical trials may show that our potential drug compounds are ineffective and/or cause harmful side effects; Â Â â— 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; Â Â â— 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; Â Â â— 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; Â Â â— our potential drug compounds may prove to be too expensive to manufacture or administer to patients; Â Â â— 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; Â Â â— even if our potential drug compounds are approved, we may not be able to produce them in commercial quantities or at reasonable costs; Â 36 Â Â Â â— even if our potential drug compounds are approved, they may not achieve commercial acceptance; Â Â â— regulatory or governmental authorities may apply restrictions to any of our potential drug compounds, which could adversely affect their commercial success; and Â Â â— the proprietary rights of other parties may prevent us or our potential collaborative partners from marketing our potential drug compounds. Â 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 researchand development plans and may be forced to cease operations.Â Our research and development plans will requiresubstantial additional future funding which could impact our operations and financial condition. Â It will take several years before we can develop potentiallymarketable products, if at all. Our research and development plans will require substantial additional capital, arising from costs to:Â Â â—Â conduct research, non-clinical testing and human clinical trials; Â Â â—Â establish pilot scale and commercial scale manufacturing processes and facilities; and Â Â â—Â establish and develop quality control, regulatory, marketing, sales, finance and administrative capabilities to support these programs. Â Our future operating and capital needs will dependon many factors, including:Â Â â— the pace of scientific progress in our research and development programs and the magnitude of these programs; Â Â â— the scope and results of pre-clinical testing and human clinical trials; Â Â â— the time and costs involved in obtaining regulatory approvals; Â Â â— the time and costs involved in preparing, filing, prosecuting, securing, maintaining and enforcing patents; Â Â â— competing technological and market developments; Â Â â— our ability to establish additional collaborations; Â Â â— changes in our existing collaborations; Â Â â— the cost of manufacturing scale-up; and Â Â â— the effectiveness of our commercialization activities. Â We base our outlook regarding the need for funds onmany uncertain variables. Such uncertainties include the success of our research initiatives, regulatory approvals, the timing of eventsoutside our direct control such as negotiations with potential strategic partners and other factors. Any of these uncertain events cansignificantly change our cash requirements as they determine such one-time events as the receipt or payment of major milestones and otherpayments.Â 37 Â Â Additional funds may be required to support our operationsand if we are unable to obtain them on favorable terms, we may be required to cease or reduce certain further research and developmentprograms of our drug product platform, sell some or all our intellectual property, merge with another entity or scale back operations.Â If we or any companion diagnostic collaboratorof ours are unable to successfully develop and obtain regulatory approval for companion diagnostic tests for our drug candidates, or experiencesignificant delays in doing so, we may not realize the commercial potential of our drug candidates.Â We analyze genomic data from clinical trials to identifybiomarkers, which we use in the analysis of our clinical trials.Â Identification of these patients will require theuse and development of companion diagnostics. According to the FDAâ€™s 2014 guidance document on In Vitro Companion Diagnostic Devices,for novel therapeutic products that depend on the use of a diagnostic test and where the diagnostic device could be essential for thesafe and effective use of the corresponding therapeutic product, the premarket application for the companion diagnostic device shouldbe developed and approved or cleared contemporaneously with the therapeutic.Â We do not have experience or capabilities in developingor commercializing diagnostics. It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility,or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data frompreclinical studies and early clinical trials appear to support development of a companion diagnostic for a drug candidate, data generatedin later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaboratorsmay encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similarto those we face with respect to our drug candidates, including issues with achieving regulatory clearance or approval, production ofsufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable tosuccessfully develop companion diagnostics for our drug candidates, or experience delays in doing so, the development of these drug candidatesmay be adversely affected, these drug candidates may not obtain marketing approval, and we may not realize the full commercial potentialof any of these therapeutics that have or may obtain marketing approval. We may not be able to enter into arrangements with another diagnosticcompany to develop and obtain regulatory approval for an alternative diagnostic test for use in connection with the development and commercializationof our drug candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercializationof our therapeutic candidates or therapeutics.Â Companion diagnostics are subject to regulation bythe FDA and comparable foreign regulatory authorities as medical devices and will likely require separate regulatory approval prior tocommercialization. If we or third parties are unable to successfully develop companion diagnostics for our drug candidates, or experiencedelays in doing so:Â Â â— the development of these drug candidates may be delayed because it may be difficult to identify patients for enrollment in

our clinical trials in a timely manner; Â Â â— these drug candidates may not receive marketing approval if their safe and effective use depends on a companion diagnostic; and Â Â â— we may not realize the full commercial potential of these drug candidates that receive marketing approval if, among other reasons, we are unable to appropriately identify patients or types of tumors targeted by these drug candidates. Â Even if our drug candidates and any associated companiondiagnostics are approved for marketing, the need for companion diagnostics may slow or limit adoption of our drug candidates. Our drugcandidates may be perceived negatively compared to alternative treatments that do not require the use of companion diagnostics, eitherdue to the additional cost of the companion diagnostic or the need to complete additional prior to administering our drug candidates.Â If any of these events were to occur, our businessand growth prospects would be harmed materially.Â 38 Â Â The regulatory approval processes of the FDAand comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, which could lead to our inabilityto generate product revenue.Â The time required to obtain approval by the FDA andcomparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials anddepends upon numerous factors, including the type, complexity and novelty of the product candidates involved. Seeking foreign regulatoryapprovals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinicaltrials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or preventthe introduction of our product candidates in those countries. In addition, approval policies, regulations or the type and amount of clinicaldata necessary to gain approval may change during the course of a product candidateâ€™s clinical development and may vary among jurisdictions,which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretionin the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and requireadditional preclinical, clinical or other data. Satisfying these and other regulatory requirements is costly, time consuming, uncertainand subject to unanticipated delays. Our failure to obtain regulatory approval in any country may delay or have negative effects on theprocess for regulatory approval in other countries. Even if we eventually complete clinical testing and receive approval of any regulatoryfiling for our product candidates, the FDA and comparable foreign regulatory authorities may approve our product candidates for a morelimited indication or a narrower patient population than we originally requested. If we fail to comply with regulatory requirements ininternational markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the fullmarket potential of our product candidates will be harmed.Â Applications for our product candidates could failto receive regulatory approval for many reasons, including but not limited to the following:Â Â·the FDA or comparable international regulatory authorities may disagree with the design, implementationor results of our clinical trials;Â Â·the FDA or comparable international regulatory authorities may determine that our product candidates arenot safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristicsthat preclude our obtaining marketing approval or prevent or limit commercial use;Â Â·the population studied in the clinical program may not be sufficiently broad or representative to assureefficacy and potency and safety in the full population for which we seek approval;Â Â·the FDA or comparable international regulatory authorities may disagree with our interpretation of datafrom preclinical studies or clinical trials;Â Â·the data collected from clinical trials of our product candidates may not be sufficient to support thesubmission of a Biologics License Application, New Drug Application or other submission or to obtain regulatory approval in the UnitedStates or elsewhere;Â Â·we may be unable to demonstrate to the FDA or comparable international regulatory authorities that a productcandidateâ€™s risk-benefit ratio for its proposed indication is acceptable;Â Â·the FDA or comparable international regulatory authorities may fail to approve the manufacturing processes,test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;andÂ Â·the approval policies or regulations of the FDA or international foreign regulatory authorities may significantlychange in a manner rendering our clinical data insufficient for approval.Â 39 Â Â In order to market any product candidates outsideof the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safetyand efficacy and potency and approval standards. Clinical trials conducted in one country may not be accepted by regulatory authoritiesin other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country.Â The ability of the FDA to review and approve new productscan be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel andaccept the payment of user fees, government shutdowns, including as a result of budget delays or other circumstances like the COVID-19pandemic and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result.This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtainregulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects.Â All but one of our clinicaltrials to date have been conducted outside the United States, and the FDA and other foreign regulatory authorities may not accept datafrom such trials.Â The acceptance of study data fromclinical trials conducted outside the United States by the FDA may be subject to certain conditions or may not be accepted at all. Incases where data from foreign clinical trials are intended to serve as the sole basis for regulatory approval in the United States, theFDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United Statespopulation and United States medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuantto good clinical practice regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA,or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriatemeans. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicablelocal laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any other foreign regulatoryauthority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparableforeign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consumingand delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercializationin the applicable jurisdiction.Â We have received Fast Track designation forone of our compounds and may seek such designation or breakthrough therapy and priority review for other compounds in the future. FastTrack designation or breakthrough therapy designation may not actually lead to a faster FDA review and approval process.Â For some of our compounds, including ANAVEXÂ®2-73,we hope to benefit from the FDAâ€™s Fast Track and priority review programs. In February 2020, the FDA granted Fast Track designationfor the ANAVEXÂ®2-73 clinical development program for the treatment of Rett syndrome. Programs with Fast Track designationmay benefit from early

and frequent communications with the FDA, potential priority review and the ability to submit a rolling applicationfor regulatory review. Fast Track designation applies to both the product candidate and the specific indication for which it is beingstudied. If any of our compounds receive Fast Track designation but do not continue to meet the criteria for Fast Track designation, orif our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinicalsupply, we will not receive the benefits associated with the Fast Track program. Furthermore, Fast Track designation does not change thestandards for approval. The receipt of Fast Track designation for a compound may not result in a faster development or regulatory reviewor approval process compared to products considered for approval under conventional FDA procedures and does not assure ultimate approvalby the FDA. In addition, even if any product candidate qualifies for Fast Track designation, the FDA may later decide that the productcandidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.Fast Track designation alone does not guarantee qualification for the FDAâ€™s priority review procedures.Â 40 Â Â Under FDA policies, a compound is eligible for priorityreview, or review within a six-month time frame from the time a complete NDA is accepted for filing, if the compound provides a significantimprovement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. The FDA determines whether a drug qualifiesfor Priority Review after an NDA for such drug is submitted to the FDA. Therefore, until NDAs are submitted for our compounds, we cannotbe assured that they will be granted Priority Review. Additionally, even if Priority Review is granted for one of our compounds, the FDAdoes not always meet its six-month PDUFA goal date for Priority Review and the review process is often extended by FDA requests for additionalinformation or clarification.Â We may seek Breakthrough Therapy designation for oneor more of our current or future compounds. Designation as a Breakthrough Therapy is largely within the discretion of the FDA. Accordingly,even if we believe that a compound meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determinenot to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result ina faster development process, review or approval compared to candidate products considered for approval underÂ non-expeditedÂ FDAreview procedures and does not assure ultimate approval by the FDA. In addition, even if one or more compounds qualify as breakthroughtherapies, the FDA may later decide that the product no longer meets the conditions for qualification and revoke the designation.Â Fast Track or Breakthrough Therapy designation forour compounds may not actually lead to a faster review process, and a delay in the review process or in the approval of our compoundswill delay revenue from their potential sales and will increase the capital necessary to fund these compound development programs.Â 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.Â Under the Orphan Drug Act, the FDA may grant orphandesignation to a drug intended to treat a rare disease or condition or for which there is no reasonable expectation that the cost of developingand making available in the United States a drug for a disease or condition will be recovered from sales in the United States for thatdrug. If a product that has orphan drug designation subsequently receives the first FDA approval for the indication for which it has suchdesignation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, includinga full NDA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showingof clinical superiority to the product with orphan drug exclusivity.Â We have received orphan drug designation for severalof our compounds, but we may not be able to obtain or maintain orphan drug exclusivity in the United States for those compounds. We maynot be the first to obtain marketing approval of any compound for which we have obtained orphan drug designation for the orphan-designatedindication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in theUnited 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 materiallydefective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the raredisease or condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moietyfor the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effectiveor makes a major contribution to patient care.Â In addition, others may obtain orphan drug exclusivity for products addressing thesame diseases or conditions as products we are developing, thus limiting our ability to compete in the markets addressing such diseasesor conditions for a significant period of time.Â Orphan drug designation neither shortensthe development time or regulatory review time of a drug nor gives the product candidate any advantage in the regulatory review or approvalprocess or entitles the product candidate to priority review.Â 41 Â Â If we fail to demonstrate efficacy in our non-clinicalstudies and clinical trials our future business prospects, financial condition and operating results will be materially adversely affected.Â The success of our research and development effortswill be greatly dependent upon our ability to demonstrate potential drug compound efficacy in non-clinical studies, as well as in clinicaltrials. Non-clinical studies involve testing potential drug compounds in appropriate non-human disease models to demonstrate efficacyand safety. Regulatory agencies evaluate these data carefully before they will approve clinical testing in humans. If certain non-clinicaldata reveals potential safety issues or the results are inconsistent with an expectation of the potential drug compoundâ€™s efficacyin humans, the regulatory agencies may require additional more rigorous testing before allowing human clinical trials. This additionaltesting will increase program expenses and extend timelines. We may decide to suspend further testing on our potential drug compoundsif, in the judgment of our management and advisors, the non-clinical test results do not support further development.Â Moreover, success in non-clinical testing and earlyclinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinicaltrials will replicate the results of prior clinical trials and non-clinical testing. The clinical trial process may fail to demonstratethat our potential drug compounds are safe for humans and effective for indicated uses. This failure would cause us to abandon a drugcandidate and may delay development of other potential drug compounds. Any delay in, or termination of, our non-clinical testing or clinicaltrials will delay the filing of an IND and NDA with the FDA or the equivalent applications with pharmaceutical regulatory authoritiesoutside the United States and, ultimately, our ability to commercialize our potential drug compounds and generate product revenues. Inaddition, we expect that our early clinical trials will involve small patient populations. Because of the small sample size, the resultsof these early clinical trials may not be indicative of future results. Also, the IND process may be extremely costly and may substantiallydelay the development of our potential drug compounds. Moreover, positive results of non-clinical tests will not necessarily indicatepositive results in subsequent clinical trials.Â Following successful non-clinical testing, potentialdrug compounds will need to be tested in a clinical development program to provide data on safety and efficacy prior to becoming eligiblefor product approval and

licensure by regulatory agencies. From the first human trial through to regulatory approval can take many yearsand 10-12 years is not unusual for certain compounds.Â If any of our future clinical development potentialdrug compounds become the subject of problems, our ability to sustain our development programs will become critically compromised. Forexample, efficacy or safety concerns may arise, whether or not justified, that could lead to the suspension or termination of our clinicalprograms. Examples of problems that could arise include, among others:Â Â â—Â efficacy or safety concerns with the potential drug compounds, even if not justified; Â Â â—Â manufacturing difficulties or concerns; Â Â â—Â regulatory proceedings subjecting the potential drug compounds to potential recall; Â Â â—Â publicity affecting doctor prescription or patient use of the potential drug compounds; Â Â â—Â pressure from competitive products; or Â Â â—Â introduction of more effective treatments. Â Each clinical phase is designed to test attributesof the drug and problems that might result in the termination of the entire clinical plan can be revealed at any time throughout the overallclinical program. The failure to demonstrate efficacy in our clinical trials would have a material adverse effect on our future businessprospects, financial condition and operating results.Â 42 Â Â If a particular product candidate causes undesirableside effects, then we may be unable to receive regulatory approval of or commercialize such product candidate.Â We may experience numerous unforeseen events during,or as a result of, the testing process that could delay or prevent commercialization of any of our product candidates, including the occurrenceof undesirable side effects. Such side effects could lead to clinical trial challenges, such as difficulties in subject recruitment, retention,and adherence, potential product liability claims, and possible termination by health authorities. These types of clinical trial challengescould in turn, delay or prevent regulatory approval of our product candidate. Side effects may also lead regulatory authorities to requirestronger product warnings on the product label, costly post-marketing studies, and/or a REMS, among other possible requirements. If theproduct candidate has already been approved, such approval may be withdrawn. Any delay in, denial, or withdrawal of marketing approvalfor one of our product candidates will adversely affect our business, including our results of operations and financial position. Evenif one or more of our product candidates receives marketing approval, undesirable side effects may limit such productâ€™s commercialviability. Patients may not wish to use our product, physicians may not prescribe our product, and our reputation may suffer. Any of theseevents may significantly harm our business and financial prospects.Â We are highly dependent on our key personnel,and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement ourbusiness strategy.Â Our ability to compete in the highly competitive biotechnologyand pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel.We are highly dependent on our management, scientific and medical personnel. The loss of the services of any of our executive officers,other key employees and other scientific and medical advisors, and an inability to find suitable replacements could result in delays inproduct development and harm our business.Â Competition for skilled personnel in our market isintense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. Despite our efforts toretain valuable employees, members of our management, scientific and development teams may terminate their employment or service withus on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment,which means that any of our employees could leave our employment at any time, with or without notice. Our success also depends on ourability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-leveland senior scientific and medical personnel in an extremely competitive market for employees and other service providers.Â If we do not obtain the support of qualifiedscientific collaborators, our revenue, growth and profitability will likely be limited, which would have a material adverse effect onour business.Â We will need to establish relationships with leadingscientists and research institutions. We believe that such relationships are pivotal to establishing products using our technologies asa standard of care for various indications. Additionally, although in discussion, there is no assurance that our current research partnerswill continue to work with us or that we will be able to attract additional research partners. If we are not able to establish scientificrelationships to assist in our research and development, we may not be able to successfully develop our potential drug compounds. If thishappens, our business will be adversely affected.Â We may not be able to develop, market or generatesales of our products to the extent anticipated. Our business may fail and investors could lose all their investment in our Company.Â Assuming that we are successful in developing ourpotential drug compounds and receiving regulatory clearances to market our products, our ability to successfully penetrate the marketand generate sales of those products may be limited by a number of factors, including the following:Â Â â—Â 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; Â 43 Â Â Â â—Â 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 Â Â â—Â 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. Â If this happens, our business will be adversely affected.Â None of our potential drug compounds may reachthe commercial market for a number of reasons and our business may fail.Â Successful research and development of pharmaceuticalproducts is high risk. Most products and development candidates fail to reach the market. Our success depends on the discovery of newdrug compounds that we can commercialize. It is possible that our products may never reach the market for a number of reasons. They maybe found ineffective or may cause harmful side effects during non-clinical testing or clinical trials or fail to receive necessary regulatoryapprovals. We may find that certain products cannot be manufactured at a commercial scale and, therefore, they may not be economical toproduce. Our potential products could also fail to achieve market acceptance or be precluded from commercialization by proprietary rightsof third parties. Our patents, patent applications, trademarks and other intellectual property may be challenged, and this may delay orprohibit us from effectively commercializing our products. Furthermore, we do not expect our potential drug compounds to be commerciallyavailable for a number of years, if at all. If none of our potential drug compounds reach the commercial market, our business will likelyfail and investors will lose all of their investment in our Company. If this happens, our business will be adversely affected.Â Material modifications in the methods of productcandidate manufacturing may result in additional costs or delay.Â As product candidates progress from preclinical studiesto late-stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program,such as manufacturing methods, materials and processes, are altered along the way in an effort to optimize yield, manufacturing batchsize, minimize costs and achieve consistent purity, identity, potency, quality and results. Such changes carry the risk that they willnot achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and

could affectplanned or other clinical trials conducted with product candidates produced using the modified manufacturing methods, materials, and processes.This could delay completion of clinical trials and could require non-clinical or clinical bridging and comparability studies, which couldincrease costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved.Â If our competitors succeed in developing productsand technologies faster or that are more effective or with a better profile than our own, or if scientific developments change our understandingof the potential scope and utility of our potential products, then our technologies and future products may be rendered undesirable orobsolete.Â We face significant competition from industry participantsthat are pursuing technologies in similar disease states to those that we are pursuing and are developing pharmaceutical products thatare competitive with our products. Nearly all of our industry competitors have greater capital resources, larger overall research anddevelopment staffs and facilities, and a longer history in drug discovery and development, obtaining regulatory approval and pharmaceuticalproduct manufacturing and marketing than we do. With these additional resources, our competitors may be able to respond to the rapid andsignificant technological changes in the biotechnology and pharmaceutical industries faster than we can. Our future success will dependin large part on our ability to maintain a competitive position with respect to these technologies. Rapid technological development, aswell as new scientific developments, may result in our products becoming obsolete before we can recover any of the expenses incurred todevelop them. For example, changes in our understanding of the appropriate population of patients who should be treated with a targetedtherapy like we are developing may limit the drugâ€™s market potential if it is subsequently demonstrated that only certain subsetsof patients should be treated with the targeted therapy.Â 44 Â Â We have advanced our research and developmentefforts on the treatment of neurodegenerative and central nervous system, or CNS, disorders, a field that has seen very limited successin product development.Â We have advanced our researchand development efforts on addressing neurodegenerative, neurodevelopmental and CNS disorders. Collectively, efforts by pharmaceuticalcompanies in the field of neurodegenerative,Â neurodevelopmentalÂ and CNS disorders have seen very limited successes in productdevelopment. The development of neurodegenerative and CNS therapies presents unique challenges, including an imperfect understanding ofthe biology, the presence of the blood brain barrier that can restrict the flow of drugs to the brain, a frequent lack of translatabilityof preclinical study results in subsequent clinical trials and dose selection, and the product candidate having an effect that may betoo small to be detected using the outcome measures selected in clinical trials or if the outcomes measured do not reach statistical significance.Â Our reliance on third parties, such as universitylaboratories, 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 or non-compliancewith regulations.Â In the course of product development, we may engageuniversity laboratories, other biotechnology companies or contract or clinical manufacturing organizations to manufacture drug materialfor us to be used in non-clinical and clinical testing and contract research organizations to conduct and manage non-clinical studiesand clinical trials. If we engage these organizations to help us with our non-clinical and clinical programs, many important aspects ofthis process have been and will be out of our direct control. If any of these organizations we may engage in the future fail to performtheir 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 andthe potential market approval of our potential drug compounds.Â In addition, any of these third parties may engagein misconduct or other improper activities, including non-compliance with regulatory standards and requirements. Misconduct by these partiescould include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulationsof any regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities;healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial informationor data accurately. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautionswe take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protectingus from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.Â If we fail to compete successfully with respectto partnering, licensing, mergers, acquisitions, joint venture and other collaboration opportunities, we may be limited in our abilityto research and develop our potential drug compounds.Â Our competitors compete with us to attract establishedbiotechnology and pharmaceutical companies or organizations for partnering, licensing, mergers, acquisitions, joint ventures or othercollaborations. 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 willthen be precluded from pursuing those specific opportunities. Since each of these opportunities is unique, we may not be able to finda 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 availableopportunities.Â Universities and public and private research institutionsalso compete with us. While these organizations primarily have educational or basic research objectives, they may develop proprietarytechnology 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, ifat all. If we are unable to compete successfully with respect to acquisitions, joint venture and other collaboration opportunities, wemay be limited in our ability to develop new products.Â 45 Â Â The use of any of our products in clinical trialsmay expose us to liability claims, which may cost us significant amounts of money to defend against or pay out, causing our business tosuffer.Â The nature of our business exposes us to potentialliability risks inherent in the testing, manufacturing and marketing of our products. We currently have one drug compound in clinicaltrials; however, when any of our products enter clinical trials or become marketed products, they could potentially harm people or allegedlyharm people possibly subjecting us to costly and damaging product liability claims. Some of the patients who participate in clinical trialsare already ill when they enter a trial or may intentionally or unintentionally fail to meet the exclusion criteria. The waivers we obtainmay not be enforceable and may not protect us from liability or the costs of product liability litigation. Although we intend to obtainproduct liability insurance, which we believe is adequate, we are subject to the risk that our insurance will not be sufficient to coversuch claims. The insurance costs along with the defense or payment of liabilities above the amount of coverage could cost us significantamounts of money and management distraction from other elements of the business, causing our business to

suffer.Â If our information systems or data, or thoseof third parties upon whom we rely, are or were compromised, our business may be adversely affected.Â In the course of our business, we, or third partiesupon whom we rely, may gather, collect, receive, use, transmit, store/retain or dispose of data and confidential information (such asconfidential employee information or health-related data), sensitive data, intellectual property and trade secrets.Â Cyberattacks, malicious internet-basedactivity, online and offline fraud and other similar activities threaten the confidentiality, integrity, and availability of our sensitiveinformation and information technology systems, and those of the third parties upon whom we rely. We, and the third parties upon whomwe may rely, may be subject to a variety of these evolving threats.Â Although we endeavor to protectconfidential information through the implementation of security technologies, processes and procedures, it is possible that an individualor group could defeat security measures and access sensitive information about our business and employees. The existence of a remote workforcealso poses increased risks to our information technology systems and data, as more of our employees work from home, utilizing networkconnections outside our premises.Â Any misappropriation, loss or other unauthorized disclosureof confidential information gathered, stored or used by us or by third parties on our behalf, could have a material impact on the operationof our business, including damaging our reputation with our employees, third parties and investors. We could also incur significant costsimplementing additional security measures and organizational changes, implementing additional protection technologies, training employeesor engaging consultants.Â Our contracts with thirdparties upon whom we may rely, may not contain limitations of liability, and even where they do, there can be no assurance that limitationsof liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and securityobligations. In addition, we could incur increased litigation as a result of any potential cyber-security breach and our insurance coveragemay not be adequate or sufficient in type or amount to protect us from or to mitigate liabilities arising out of our privacy and securitypractices.Â We are not aware that we have experienced any materialmisappropriation, loss or other unauthorized disclosure of confidential or personally identifiable information as a result of a cyber-securitybreach or other act, however, a cyber-security breach or other act and/or disruption to our information technology systems could havea material adverse effect on our business, prospects, financial condition or results of operations.Â Even if we receive regulatory approval for oneor more compounds, we will be subject to continuing regulatory obligations and ongoing regulatory review, which may result in significantadditional expense. Additionally, our compounds, if approved, could be subject to labeling and other restrictions on marketing or withdrawalfrom the market, and we may be subject to penalties, if we fail to comply with regulatory requirements or if we experience unanticipatedproblems with our compounds, when and if any of them are approved. Â 46 Â Â Following potential approval of any our compounds,the FDA may impose significant restrictions on a drugâ€™s indicated uses or marketing or require potentially costly and time-consumingpost-approval studies, post-market surveillance or clinical trials to monitor the safety and efficacy of the drug. The FDA may also requirea Risk Evaluation and Mitigation Strategy (â€œREMSâ€) as a condition of approval of one or more of our compounds, which couldinclude requirements for a medication guide, physician communication plans or additional elements to ensure safe use of the drug. AdditionalREMS elements may include restricted distribution methods, patient registries and other risk minimization tools.Â In addition, if the FDA or a comparable foreign regulatoryauthority 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 potentiallyextensive 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, orwith our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, amongother things:Â Â â— restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls; Â Â â— fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials; Â Â â— restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials; Â Â â— product seizure or detention, or refusal to permit the import or export of our products; Â Â â— injunctions or the imposition of civil or criminal penalties; and Â Â â— refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals. Â The occurrence of any event or penalty described abovemay limit our ability to commercialize our compounds and generate revenue and could require us to expend significant time and resourcesin response or generate negative publicity.Â If any of our compounds are approved, our productlabeling, advertising and promotion will also be subject to regulatory requirements and ongoing regulatory review. The FDA strictly regulatesthe promotional claims that may be made about drug products. In particular, a drug may not be promoted for uses that are not approvedby the FDA as reflected in the drugâ€™s approved labeling. If we receive marketing approval for a compound, physicians may neverthelesslawfully prescribe it to their patients in a manner that is inconsistent with the approved label. While the FDA recently clarified thatmere knowledge that a physician is prescribing an approved 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 federalgovernment has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companiesfrom engaging in off-label promotion. Additionally, promotion for off-label uses could result in significant liability under the FalseClaims Act. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotionalconduct is changed or curtailed.Â The FDAâ€™s and other regulatory authoritiesâ€™policies are subject to change at any time, and additional government regulations may be enacted that could prevent, limit or delay regulatoryapproval of our compounds. If we are unable to timely adapt to changes in existing requirements or the adoption of new requirements orpolicies, or if we are not able to maintain regulatory compliance post-marketing, we may lose any marketing approval that we may haveobtained, and we may not achieve or sustain profitability.Â 47 Â Â Finally, we cannot predict the likelihood, natureor extent of government regulation that may arise from future legislation or administrative or executive action, either in the UnitedStates or abroad. It is difficult to predict how any such legislative, administrative or executive actions will be implemented, and theextent to which they will impact the FDAâ€™s ability to exercise its regulatory authority. If these legislative or executive actionsimpose constraints on the FDAâ€™s ability to engage in oversight and implementation activities in the normal course, our businessmay be negatively impacted.Â Changes in funding for the FDA, the SEC andother government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and servicesfrom being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on

whichthe operation of our business may rely, which could negatively impact our business.Â The ability of the FDA to review and approve new productscan be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel andaccept payment of user fees, statutory, regulatory and policy changes, and business disruptions, such as those caused by the COVID-19pandemic. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC andother government agencies on which our operations may rely, including those that fund research and development activities is subject tothe political process, which is inherently fluid and unpredictable.Â Disruptions at the FDA and other agencies may alsoslow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect ourbusiness. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, suchas the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolongedgovernment shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions,which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access thepublic markets and obtain necessary capital in order to properly capitalize and continue our operations.Â We receiveÂ AustralianÂ government researchand development incomeÂ taxÂ incentive refunds. If our research and development expenditures are not deemed to be eligible forthe refund, proposed modifications to theÂ taxÂ incentive program are enacted, or theÂ taxÂ incentive program is discontinuedby theÂ AustralianÂ government, it could have a negative effect on our future cash flows and the funding of future research anddevelopment projects.Â Our subsidiary, Anavex Australia Pty Ltd., is incorporatedin Australia where we are currently engaged in research and development activities for ANAVEXÂ®2-73 and ANAVEXÂ®3-71.Our subsidiary is eligible to participate in theÂ AustralianÂ Federal Governmentâ€™s Research and DevelopmentÂ TaxÂ Incentiveprogram, under which the government provides a cash refund for a portion of eligible research and development expenditures (currently43.5% to 48.5% depending on the entityâ€™s corporate tax rate) by smallÂ AustralianÂ entities, which are defined asÂ AustralianÂ entitieswith less than $20 million (Australian) in revenue.Â The Research and DevelopmentÂ TaxÂ Incentiverefund is offered by theÂ AustralianÂ federal government for eligible research and development purposes based on the filing ofan annual application. As part of this program, our subsidiary applied for and received cash refunds from theÂ AustralianÂ TaxationOffice, or the ATO, for a percentage of the research and development costs expended by our subsidiary in Australia. Since the fiscal yearended September 30, 2015, we have been receiving Research and DevelopmentÂ TaxÂ Incentive refunds related to research and developmentexpenditures made.Â Certain research and development expenses incurredoutside of Australia are also eligible for theÂ AustralianÂ research and developmentÂ taxÂ incentive program, providedwe obtain an Advance Overseas Finding from AusIndustry, a division of the Australian Governmentâ€™s Department of Industry, Innovationand Science (â€œAusIndustryâ€).Â To receive an Advance Overseas Finding, the expenses must have been for eligible researchand development activities, as determined by AusIndustry, and the expenditures must have a scientific link to theÂ AustralianÂ activities,be unable to be conducted in Australia and the total actual and reasonably anticipated overseas costs must be expected to be less thanthe total actual and reasonably anticipated expenditures for activities conducted within Australia, as determined by AusIndustry at thetime of application for an Advance Overseas Finding (â€œOSFâ€).Â 48 Â Â This OSF binds both AusIndustryand the Commissioner of Taxation for three income years. However, for compliance purposes, specific issue guidance jointly issued by AusIndustryand the ATO in 2014 provides that an OSF can apply for the duration of the overseas activity provided the activities are not new or materiallydifferent than the activities described in the OSF. Currently, the Company is outside of the binding three-year period with respect toOSF applicable to some of its programs being claimed in Australia.Â To the extent that some or all of our research anddevelopment expenditures are deemed to be â€œineligible,â€ then our refunds may decrease or be eliminated. In addition, theÂ AustralianÂ governmentmay in the future modify the requirements of, reduce the amounts of the refunds available under, or discontinue the Research and DevelopmentÂ TaxÂ Incentiveprogram. Any such change to our anticipated refunds or change to the Research and DevelopmentÂ TaxÂ Incentive program would havea negative effect on our future cash flows.Â A variety of risks are associated with operatingour business internationally which could materially adversely affect our business.Â We are presently conducting clinical development solelyin Australia, United Kingdom, The Netherlands, Germany and Canada and may choose to conduct additional international and U.S. clinicaltrials in the future. Additionally, while we have not taken any steps to enter into any non-U.S. markets, we may do so in the future.Accordingly, we are subject to risks related to operating in foreign countries, including:Â Â â— different standards of care in various countries that could complicate the evaluation of our product candidates; Â Â â— different United States and foreign drug import and export rules; Â Â â— reduced protection for intellectual property rights in certain countries; Â Â â— unexpected changes in tariffs, trade barriers and regulatory requirements; Â Â â— economic weakness, including inflation, or political instability in particular foreign economies and markets; Â Â â— compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad; Â Â â— compliance with the FCPA and other anti-corruption and anti-bribery laws; Â Â â— foreign taxes, including withholding of payroll taxes; Â Â â— foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; Â Â â— workforce uncertainty in countries where labor unrest is more common than in the United States; Â Â â— production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; Â Â â— different payor reimbursement regimes, governmental payors or patient self-pay systems and price controls; Â Â â— potential liability resulting from development work conducted by foreign partners; Â Â â— business interruptions resulting from natural disasters, outbreaks of contagious diseases, such as COVID-19, or geopolitical actions, including war and terrorism, or systems failure including cybersecurity breaches; and Â Â â— compliance with evolving and expansive foreign regulatory requirements, including data privacy laws (such as the GDPR). Â 49 Â Â Additionally, in connection with the ongoing conflictbetween Russia and Ukraine, the U.S. government and European Union countries have imposed enhanced export controls on certain productsand sanctions on certain industry sectors and parties in Russia. The U.S. government has also indicated it will consider imposing additionalsanctions and other similar measures in the near future. Although we do not currently conduct any clinical trials in Russia or Ukraine,further escalation of geopolitical tensions could have a broader impact that expands into other markets where we do business or conductcertain research and development operations, which could adversely affect our business, our supply chain for our product candidates, ourcollaborators or our ability to carry out our clinical trials.Â Our abilityto use our net operating loss (â€œNOLâ€) carryforwards and certain tax credit carryforwards may be subject to limitation.Â As of September 30, 2024, we had approximately $128.5million of U.S. federal and $16.9 million of state and local NOL carryforwards. We had

approximately $16.6 million of NOL carryforwardsin Australia as of the same period. Our NOL carryforwards are subject to review and possible adjustment by the U.S. and state tax authorities.In addition, under Sections 382 and 383 of the Internal Revenue Code and corresponding provisions of state law, if a corporation undergoesan â€œownership change,â€ which is generally defined as a greater than 50% change (by value) in its equity ownership over a three-yearperiod, the corporationâ€™s ability to use its pre-change NOL carryforwards and research and development credits to offset its post-changeincome may be limited. This could limit the amount of NOLs or research and development credit carryforwards that we can utilize annuallyto offset future taxable income or tax liabilities. Subsequent ownership changes and changes to the U.S. tax rules in respect of the utilizationof NOLs and research and development credits carried forward may further affect the limitation in future years. In addition, at the statelevel, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increasestate taxes owed.Â We conducted a Section 382 study during the year endedSeptember 30, 2021 and determined that, during the year ended September 30, 2015, there was a change in ownership which resulted in $25.8million of federal NOLs being subject to an annual limitation. During the year ended September 30, 2021, we reduced our federal NOLs by$12.1 million and our research and development tax credit carryforwards by $0.8 million, which are the amount of tax assets that willexpire unutilized pursuant to the Section 382 study. This resulted in a reduction of $2.5 million of NOLs and $0.8 million of researchand development credits and a corresponding reduction in the valuation allowance of $3.3 million, which was recorded in the 2021 fiscalyear. Subsequent ownership changes in future years could trigger additional limitations of our NOLs. During the year ended September 30,2024 and 2023, we determined that there were no changes in ownership pursuant to Section 382.Â We are subject to healthcare laws and regulationswhich may require substantial compliance efforts and could expose us to criminal sanctions, civil and administrative penalties, contractualdamages, reputational harm and diminished profits and future earnings, among other penalties.Â Healthcare providers, physicians and others will playa primary role in the recommendation and prescription of our products, if approved. Our arrangements with such persons and third-partypayors and our general business operations will expose us to broadly applicable fraud and abuse and other healthcare laws and regulationsthat may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute ourdrugs, if we obtain marketing approval. Restrictions under applicable U.S. federal, state and foreign healthcare laws and regulationsinclude, but are not limited to, the following:Â Â Â â— the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, including any kickback, bribe or rebate, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase or lease, order or recommendation of, any item, good, facility or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid; Â 50 Â Â Â Â â— U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the civil False Claims Act, which impose criminal and civil penalties, including those from civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government; Â Â Â â— The Stark Law prohibits a physician from making referrals for certain â€œdesignated health servicesâ€ 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. Â Â Â â— HIPAA, which among other things, created additional federal criminal statutes that impose criminal and civil liability for, such actions as executing or attempting to execute a scheme to defraud any healthcare benefit program or knowingly and willingly falsifying, concealing or covering up a material fact or making false statements relating to healthcare matters; Â Â Â â— The privacy and security provisions of HIPAA, which impose certain requirements on covered entities and their business associates, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; Â Â Â â— U.S. federal transparency requirements under the Physician Payments Sunshine Act, enacted as part of the Affordable Care Act that require applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Childrenâ€™s Health Insurance Program, with specific exceptions, to track and annually report to CMS payments and other transfers of value provided to physicians, certain other healthcare providers (such as physicians assistants and nurse practitioners),and teaching hospitals, as well as ownership and investment interests held by physicians or their immediate family members; and Â Â Â â— analogous state or foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, state marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements, state laws that require biopharmaceutical companies to comply with the biopharmaceutical industryâ€™s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA, thus complicating compliance efforts. Â Ensuring that our business arrangements with thirdparties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities willconclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraudand abuse or other healthcare laws and regulations. If our operations were found to be in violation of any of these laws or any othergovernmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages,fines, disgorgement, imprisonment, possible exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractualdamages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could substantiallydisrupt our operations. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliancewith applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government fundedhealthcare programs. We may incur significant costs achieving and maintaining compliance with applicable federal and state privacy, security,and fraud laws. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incursignificant legal expenses and divert our attention from the operation of our business.Â 51 Â Â We expect current and future legislation affectingthe pharmaceutical industry, including drug pricing reform, to impact our business generally, which could adversely affect our businessoperations. Â In the United States, there have been, and continueto be proposed and

enacted legislation at the federal and state levels designed to, among other things, bring more transparency to drugpricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reformgovernment program reimbursement methodologies for drugs. For example, in July 2021, the Biden administration released an executive order,â€œPromoting Competition in the American Economy,â€ with multiple provisions aimed at prescription drugs. In response to Bidenâ€™sexecutive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles fordrug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrativeactions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price ofcertain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D topenalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, althoughthey may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impacton the pharmaceutical industry. If any of our products are subject to such negotiation, we may lose a significant amount of the revenuesexpected during the full life cycle of these products. Further, the Biden administration released an additional executive order on October14, 2022, directing HHS to submit a report within 90 days on how the Center for Medicare and Medicaid Innovation can be further leveragedto test new models for lowering drug costs for Medicare and Medicaid beneficiaries. WeÂ expect that additional U.S. federal healthcarereform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcareproducts and services, which could result in reduced demand for our product candidates or additional pricing pressures.Â The coverage and reimbursement status of newlyapproved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved,could limit our ability to market those products and decrease our ability to generate product revenue.Â Significant uncertainty exists as to the coverageand reimbursement status of any compound for which we may seek regulatory approval. Sales in the United States will depend in part onthe availability of sufficient coverage and adequate reimbursement from third-party payors, which include government health programs suchas 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 denialby payors.Â The process for determining whether a payor will providecoverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product.A payorâ€™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 Medicarecoverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods andapproval processes. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. If coverage and adequatereimbursement are not available, or are available only at limited levels, successful commercialization of, and obtaining a satisfactoryfinancial return on, any product we develop may not be possible.Â Third-party payors are increasingly challenging theprice 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 studiesin order to demonstrate the medical necessity and cost-effectiveness of any products, which would be in addition to the costs expendedto obtain regulatory approvals. Third-party payors may not consider our compounds to be medically necessary or cost-effective comparedto other available therapies, or the rebate percentages required to secure favorable coverage may not yield an adequate margin over costor may not enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development. Additionally,we or our collaborators may develop companion diagnostic tests for use with our product candidates. Companion diagnostic tests requirecoverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products.Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companiondiagnostics. Our inability to promptly obtain coverage and adequate reimbursement from third-party payors for the product candidates,and for us or our collaborators to obtain coverage and adequate reimbursement for related companion diagnostic tests that may be developed,could have a material and adverse effect on our business, financial condition, results of operations and prospects.Â 52 Â Â Risks Related to our Common StockÂ A decline in the price of our common stock couldaffect our ability to raise further working capital and adversely impact our operations and would severely dilute existing or future investorsif we were to raise funds at lower prices.Â A prolonged decline in the price of our common stockcould 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 toraise equity capital in the future would force us to reallocate funds from other planned uses and would have a significant negative effecton our business plans and operations, including our ability to develop new products and continue our current operations. If our stockprice declines, there can be no assurance that we can raise additional capital or generate funds from operations sufficient to meet ourobligations. We believe the following factors could cause the market price of our common stock to continue to fluctuate widely and couldcause our common stock to trade at a price below the price at which you purchase your shares of common stock:Â Â â— actual or anticipated variations in our quarterly operating results; Â Â â— announcements of new services, products, acquisitions or strategic relationships by us or our competitors; Â Â â— changes in accounting treatments or principles; Â Â â— changes in earnings estimates by securities analysts and in analyst recommendations; and Â Â â— general political, economic, regulatory and market conditions. Â The market price for our common stock may also beaffected 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.Â If we issue additional shares of common stockin the future, it will result in the dilution of our existing stockholders and may cause the share price of our common stock to fall.Â We have 200,000,000 shares of common stock authorizedfor issuance and we also have 10,000,000 shares of preferred stock authorized. Our Board of Directors has the authority to issue additionalshares of preferred and common stock up to the authorized capital stated in the articles of incorporation. Our Board of Directors maychoose 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 sharesof our common stock. If we do issue any such additional shares of common stock, such issuance also will cause a reduction in the proportionateownership 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 stockholder dilution and may cause ourshare price to fall.Â Our stock price has been volatile and may bevolatile in the future.Â Our stock price has been volatile at certain timeshistorically, and may be volatile in the future. We may incur rapid and substantial increases or decreases in our stock price in the foreseeablefuture that do not coincide in timing with the disclosure of news or developments by us. The stock market in general, and the market forbiotechnology and pharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operatingperformance of particular companies. The market price for our common stock may be influenced by many factors, including the following:Â 53 Â Â Â â— announcements of new data, clinical trial results or those of companies that are perceived to be similar to us; Â Â Â Â â— announcements related to any delays in any preclinical or clinical trials related to our products; Â Â Â Â â— announcements related to our productsâ€™ ability to demonstrate efficacy or an acceptable safety profile of our product candidates or similar announcements by companies that are perceived to be similar to us; Â Â Â Â â— our ability to meet or exceed expectations of analysts or investors; Â Â Â Â â— news that 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; Â Â Â Â â— actions taken by regulatory agencies with respect to our product candidates or the progress of our clinical trials, including with respect to any fast track or orphan drug designations; Â Â Â Â â— announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration partners or our competitors; Â Â Â Â â— grants awarded to us or companies that are perceived to be similar to us from outside entities; Â Â Â Â â— variations in our financial results or those of companies that are perceived to be similar to us; Â Â Â Â â— trading volume of our common stock; Â Â Â Â â— developments concerning our collaborations or partners; Â Â Â Â â— the impact of the COVID-19 outbreak and its effect on us; Â Â Â Â â— the perception of the biotechnology or pharmaceutical industries by the public, legislatures, regulators and the investment community; Â Â Â Â â— developments or disputes concerning intellectual property rights; Â Â Â Â â— significant lawsuits, including patent or stockholder litigation; Â Â Â Â â— our ability or inability to raise additional capital and the terms on which we raise it; Â Â Â Â â— sales of our common stock by us or our stockholders; Â Â Â Â â— declines in the market prices of stocks generally or of companies that are perceived to be similar to us; and Â Â Â Â â — general economic, industry and market conditions. Â In addition, companies trading in the stock marketin general, and The Nasdaq Capital Market in particular, have experienced extreme price and volume fluctuations that have often been unrelatedor disproportionate to the operating performance of these companies. These broad market and industry factors may seriously harm the marketprice of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securitiesclass-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantialcosts and diversion of managementâ€™s attention and resources, which could materially and adversely affect our business, financialcondition, results of operations and growth prospects. There can be no guarantee that our stock price will remain at current prices.Â 54 Â Â Our common stock may become the target of aâ€œshort squeeze.â€Â Securities of certain companies have experienced significantand extreme volatility in stock price due to short sellers of shares of common stock, known as a â€œshort squeeze.â€ These shortsqueezes have caused extreme volatility in those companies and in the market and have led to the price per share of those companies totrade at a significantly inflated rate that is disconnected from the underlying value of the company. Many investors who have purchasedshares in those companies at an inflated rate face the risk of losing a significant portion of their original investment as the priceper share has declined steadily as interest in those stocks have abated. There can be no assurance that we will not in the future be atarget of a short squeeze, and you may lose a significant portion or all of your investment if you purchase our shares at a rate thatis significantly disconnected from our underlying value.Â If we fail to maintain an effective system ofinternal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result,stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price ofour common stock.Â Pursuant to Section 404 of the Sarbanes-Oxley Act,our management is required to report upon the effectiveness of our internal control over financial reporting. We cannot assure you thatthere will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Anyfailure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition,results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, orif our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internalcontrol over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the marketprice of our common stock could decline, and we could be subject to sanctions or investigations by the Nasdaq Stock Market, the SEC orother regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implementor maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.Â Our disclosure controls and procedures may notprevent or detect all errors or acts of fraud.Â We are subject to the periodic reporting requirementsof the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reportswe file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reportedwithin the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internalcontrols and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectivesof the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and thatbreakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail todisclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controlscan be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls.Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.Â Risks Related to our Intellectual PropertyÂ If we are unable to obtain and maintain sufficientintellectual property protection for our product candidates, or if the scope of the intellectual property protection obtained is not sufficientlybroad, our competitors could develop and commercialize product candidates similar or identical to ours, and our ability to successfullycommercialize our product candidates that we may pursue may be impaired. Â Our success depends in large part on our ability toobtain and maintain protection of our intellectual property, particularly patents, in the United States and other countries with respectto our product candidates and technology. We seek to protect our proprietary

position by filing patent applications in the United Statesand abroad related to our product candidates or by in-licensing intellectual property. U.S. patents related to ANAVEXÂ®2-73are directed to ANAVEXÂ®2-73 in its various optical or crystal forms, its therapeutic indications, and dosage forms comprising certaindoses of ANAVEXÂ®2-73 combined with another therapeutic agent. We may not be able to obtain broader scope patent protectionfor ANAVEXÂ®2-73 as a single drug or in other jurisdictions.Â 55 Â Â The patent position of biotechnology and pharmaceuticalcompanies generally is highly uncertain, involves complex legal, technological and factual questions and has in recent years been thesubject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of theUnited States, or vice versa. Further, we may not be aware of all third-party intellectual property rights potentially relating to and/orinterfering with our product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries,and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in somecases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents orpending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope,validity, enforceability and/or commercial value of our patent rights are highly uncertain. Our pending and future patent applicationsmay not result in patents being issued that protect our product candidates, in whole or in part, or which could effectively prevent othersfrom commercializing competitive product candidates. Even if our patent applications issue as patents, they may not issue in a form thatwill provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitiveadvantage. Our competitors may be able to circumvent our patents by developing similar or alternative product candidates in a non-infringingmanner.Â Moreover, we may be subject to a third-party pre-issuancesubmission 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 ofothers. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patentrights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or result inour inability to manufacture or commercialize drugs without infringing on third-party patent rights. In addition, if the breadth or strengthof protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies fromcollaborating with us to license, develop or commercialize current or future product candidates.Â In addition, the issuance of a patent is not conclusiveas to its inventorship, scope, validity and/or enforceability, and our patents may be challenged in the courts or patent offices in theUnited 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 similaror identical product candidates, or limit the duration of the patent protection of our product candidates. Given the amount of time requiredfor the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before orshortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to excludeothers from commercializing drugs similar or identical to ours.Â We hold ownership or exclusive rights to twenty-twoU.S. patents, twenty-three U.S. patent applications, and various PCT or ex-U.S. patent applications relating to our drug candidates, methodsassociated therewith, and to our research programs. Neither patents nor patent applications ensure the protection of our intellectualproperty for a number of reasons, including the following:Â Â 1. Competitors may interfere with our patenting process in a variety of ways. Competitors may claim that we are 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. Â 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. Â 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). Â 4. We are 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 us less attractive to potential partners.Â 56 Â Â Â 5. Defending a patent lawsuit takes significant time and can be very expensive. Â 6. If a court decides that an Anavex compound, its method of manufacture or use, infringes on a competitorâ€™s patent, we may have to pay substantial damages for infringement. Â 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. Â 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. Â It is also unclear whether our trade secrets are adequatelyprotected. While we use reasonable efforts to protect our trade secrets, our employees or consultants may unintentionally or willfullydisclose our information to competitors. Enforcing a claim that someone illegally obtained and is using our trade secrets, like patentlitigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimesless willing to protect trade secrets. Our competitors may independently develop equivalent knowledge, methods and know-how.Â We may also support and collaborate in research conductedby government organizations, hospitals, universities or other educational institutions. These research partners may be unable or unwillingto grant us exclusive rights to technology or products derived from these collaborations.Â If we do not obtain required intellectual propertylicenses or rights, we could encounter delays in our product development efforts while we attempt to design around other patents or evenbe prohibited from developing, manufacturing or selling potential drug compounds requiring these rights or licenses. There is also a riskthat 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.Â Patent terms may be inadequate to protect ourcompetitive position on our product candidates for an adequate amount of time.Â Patents have a limited lifespan. In the United States,if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisionalfiling date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patentscovering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products,including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new productcandidates, patents protecting such candidates might expire

before or shortly after such candidates are commercialized. As a result, ourowned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similaror identical to ours.Â Depending upon the timing, duration and specificsof FDA marketing approval of product candidates that we identify, one of the U.S. patents covering such product candidate or the use thereofmay be eligible for up to five years of patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of onepatent to be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patentterm extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only thoseclaims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extensionalso may be available in certain foreign countries upon regulatory approval of our product candidates. Nevertheless, we may not be grantedpatent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligenceduring the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expirationof relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope ofpatent protection during any such extension, afforded by the governmental authority could be less than what we request. If we are unableto obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which wewill have the right to exclusively market our product may be shortened and our competitors may obtain approval of competing products followingour patent expiration sooner, and our revenue could be reduced, possibly materially.Â 57 Â Â Also, there are detailed rules and requirements regardingthe patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations, or theOrange Book. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirementsfor listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, ora manufacturer of generic drugs may challenge the listing. If one of our product candidates is approved and a patent covering that productcandidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviatednew drug application filed with the FDA to obtain permission to sell a generic version of such product candidate.Â If we fail to comply with our obligations inthe agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our businessrelationships with our licensors, we could lose intellectual property rights that are important to our business.Â We are party to an exclusive license agreement withLife Science Research Israel Ltd., with respect to certain in-licensed intellectual property related to our ANAVEXÂ®3-71product candidate, and we may need to obtain additional licenses from others in the future. Our license agreement with Life Science ResearchIsrael Ltd. imposes, and we expect that future license agreements will impose, various development, diligence, commercialization, andother obligations on us. In spite of our efforts, our licensors might conclude that we have materially breached our obligations undersuch license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop andcommercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patentsfail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, andto market, products identical to ours and we may be required to cease our development and commercialization of ANAVEXÂ®3-71or other product candidates covered by any such future licenses. Any of the foregoing could have a material adverse effect on our competitiveposition, business, financial conditions, results of operations, and prospects.Â Moreover, disputes may arise regarding intellectualproperty subject to a licensing agreement, including:Â Â â— the scope of rights granted under the license agreement and other interpretation-related issues; Â Â â— 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; Â Â â— the sublicensing of patent and other rights under our collaborative development relationships; Â Â â— our diligence obligations under the license agreement and what activities satisfy those diligence obligations; Â Â â— 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 Â Â â— the priority of invention of patented technology. Â In addition, the agreements under which we currentlylicense intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptibleto multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe tobe the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or otherobligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, resultsof operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability tomaintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affectedproduct candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.Â 58 Â Â If we do not obtain required intellectual propertylicenses or rights, we could encounter delays in our product development efforts while we attempt to design around other patents or evenbe prohibited from developing, manufacturing or selling potential drug compounds requiring these rights or licenses. There is also a riskthat 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.Â Third-party claims of intellectual propertyinfringement may prevent or delay our development and commercialization efforts.Â Our success will also depend in part on our abilityto commercialize our compounds without infringing the proprietary rights of others. However, our research, development and commercializationactivities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlledby third parties. We have not conducted extensive freedom of use patent searches and no assurance can be given that patents do not existor could be issued which would have an adverse effect on our ability to market our technology or maintain our competitive position withrespect to our technology. Because patent applications can take many years to issue, there may be currently pending patent applicationswhich may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in thefuture and claim that use of our technologies infringes upon these patents. If our compounds or other subject matter are claimed underother United States patents or other international patents or are otherwise protected by third party proprietary rights, we may be subjectto infringement actions. In such event, we may challenge the validity of such patents or other proprietary rights, or we may be requiredto obtain licenses from such companies in order to develop, manufacture or market our technology. There can be no assurances that we wouldbe successful in a challenge or be able to obtain such licenses or that such licenses, if available, could be obtained on commerciallyreasonable terms. Furthermore, the failure to succeed in a challenge, develop a commercially viable alternative or obtain needed

licensescould be materially adverse. Adverse consequences include delays in marketing some or all of our potential drug compounds based on ourdrug 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, substantialcosts 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 developmentof our technology.Â Parties making claims against us may obtain injunctiveor other equitable relief, which could effectively block our ability to further develop and commercialize ANAVEXÂ®2-73 orour other product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and wouldbe a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, wemay have to pay substantial damages, including treble damages and attorneysâ€™ fees for willful infringement, pay royalties, redesignour infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetaryexpenditure. Additionally, parties making claims against us may be able to sustain the costs of complex patent litigation more effectivelythan we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required inconnection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential informationcould be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation couldhave a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, resultsof operations, financial condition and prospects.Â If we are unable to protect the confidentialityof our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.Â While we use reasonable efforts to protect our tradesecrets, our employees or consultants may unintentionally or willfully disclose our information to competitors. Enforcing a claim thatsomeone illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome isunpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Our competitors mayindependently develop equivalent knowledge, methods and know-how.Â 59 Â Â We seek to protect our confidential proprietary information,in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractorsand collaborators. These agreements are designed to protect our proprietary information. However, we cannot be certain that such agreementshave been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary informationwill not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalentinformation and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, includingour trade secrets, and we may not be able to obtain adequate remedies for such breaches. We also seek to preserve the integrity and confidentialityof our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of ourinformation technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietaryinformation were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitorfrom using that technology or information to compete with us, which could harm our competitive position.Â We may be subject to claims that our employees,consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employeeshave wrongfully used or disclosed alleged trade secrets of their former employers.Â As is common in the biotechnology and pharmaceuticalindustry, we employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, includingour competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do notuse the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultantsor independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietaryinformation, of any of our employeeâ€™s former employer or other third parties. Litigation may be necessary to defend against theseclaims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rightsor personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation couldresult in substantial costs and be a distraction to management and other employees.Â We may become involved in lawsuits to protector enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful and could harm our business.Â Competitors may infringe our patents or other intellectualproperty. Although we are not currently involved in any litigation, if we were to initiate legal proceedings against a third party toenforce a patent covering ANAVEXÂ®2-73 or our other product candidates, the defendant could counterclaim that the patentcovering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleginginvalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of severalstatutory requirements, including lack of novelty, obviousness, written description or non-enablement. Grounds for an unenforceabilityassertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, ormade a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.Â Interference or derivation proceedings provoked bythird parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patentsor patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rightsto it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonableterms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigationor interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our managementand other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability toraise 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 ANAVEXÂ®2-73 or our other product candidates to market.Â 60 Â Â We may be subject to claims challenging theinventorship of our patents and other intellectual property.Â We or our licensors may be subject to claims thatformer employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectualproperty as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligationsof employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend againstthese and other claims challenging inventorship or our or our licensorsâ€™ ownership of our owned or

in-licensed patents, trade secretsor other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we maylose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important toour product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and bea distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financialcondition, results of operations and prospects.Â Obtaining and maintaining our patent protectiondepends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patentagencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.Â Periodic maintenance fees, renewal fees, annuity feesand various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patentagencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in placeto 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. patentagencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, feepayment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to helpus 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 applicablerules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resultingin partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter themarket and this circumstance would have a material adverse effect on our business.Â We may not be able to protect our intellectualproperty rights throughout the world.Â Filing, prosecuting and defending patents on our productcandidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countriesoutside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do notprotect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be ableto prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing productsmade using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictionswhere we have not obtained patent protection to develop their own products and may also export infringing products to territories wherewe have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our productsand our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.Â Changes in patent law could diminish the valueof our patents and patent applications in general, thereby impairing our ability to protect our product candidates.Â Changes in either the patent laws or interpretationof the patent laws in the United States and other countries could increase the uncertainties and costs surrounding the prosecution ofpatent applications and the enforcement or defense of issued patents. After March 2013, under the Leahy-Smith America Invents Act, orthe America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assumingthat other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on aninvention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent applicationin the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made theinvention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patentapplication. Since patent applications in the United States and most other countries are confidential for a period of time after filingor until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to ourproduct candidates or (ii) invent any of the inventions claimed in our or our licensorâ€™s patents or patent applications. The AmericaInvents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affectpatent litigation. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding theprosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents,all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.Â 61 Â Â In addition, the patent positions of companies inthe development and commercialization of pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed thescope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combinationof events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actionsby the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable waysthat could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual propertyin the future.Â The risk factors disclosed in this Annual Report onForm 10-K could materially and adversely affect our business, financial condition and results of operations. The risks described hereinare not the only risks we face. Our operations could also be affected by additional factors that are not presently known to us or by factorsthat we currently consider immaterial to our business.Â ITEM 1B. UNRESOLVED STAFFCOMMENTSÂ None.Â ITEM 1C. CYBERSECURITYÂ Risk management and strategy Â We have implemented and maintain various informationsecurity processes designed to identify, assess and manage material risks from cybersecurity threats to our cloud networks, third partyhosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential informationthat is proprietary, strategic or competitive in nature, and data related to our clinical trials and products.Â We have processes designed to protect our informationsystems, data, assets, infrastructure, and computing environments from cybersecurity threats and risks. Our cybersecurity strategy includesthe use of third-party IT professionals to assess the effectiveness of our cybersecurity practices for possible cybersecurity threatsand to manage our IT systems to mitigate these threats. We also use multi-factor authentication, maintain logical, physical and technicalcontrols designed to deter, prevent, mitigate and respond to cybersecurity threats. Further, we provide periodical cybersecurity remindersto our employees to emphasize the importance of adherence to our security policies. We also carry a separate cybersecurity commercialinsurance policy covering the potential financial losses that may occur in the event we experience a cybersecurity incident.Â Our assessment and management of material risks fromcybersecurity threats are integrated into the Companyâ€™s overall risk management processes. We conduct organizational risk assessmentscommensurate with our size and complexity of our operations. We are in a continuous process of reviewing and implementing incrementalinformation technology strategies to mitigate cybersecurity risks as new risks arise and as our operations evolve. This has led us toengage third party professionals to assist in the implementation of processes to manage these risks. We also use third-party service providersacross a variety of functions throughout our business, such as application providers, hosting companies,

contract research organizations,contract manufacturing organizations, distributors, and supply chain resources. We have a vendor management process to help manage cybersecurityrisks associated with our use of certain of these providers. For certain vendors, these processes include a comprehensive vendor auditprocess.Â As of the date of this Annual Report, we do not believethat any past cybersecurity incidents that have been detected have materially affected, or are reasonably likely to materially affect,our business strategy, results of operations, or financial condition.Â See â€œRisk Factors - Risks Related to OurBusiness and Operationsâ€ for additional information about the risks to our business associated with cybersecurity or a breachor compromise to our information security systems.Â 62 Â Â Governance Â Our board of directors addresses the Companyâ€™scybersecurity risk management as part of its general oversight function. The audit committee of the board of directors is responsiblefor overseeing the Companyâ€™s cybersecurity risk management processes, including oversight of mitigation of risks from cybersecuritythreats. The audit committee receives periodic reports from senior management concerning the Companyâ€™s significant cybersecuritythreats and risk and the processes the Company has implemented to address them.Â Currently we have two cybersecurity experts on ourAudit CommitteeÂ ITEM 2. PROPERTIESÂ We do not own any real property. We maintain a corporatehead office at 630 5th Avenue, 20th Floor, New York, NY, USA. Our lease costs for this office are approximately $11,000 per month. Webelieve our offices are suitable and adequate to operate our business currently, as they provide us with sufficient space to conduct ouroperations.Â ITEM 3. LEGAL PROCEEDINGSÂ The Company is subject to claims and legal proceedingsthat arise during the course of business. The Company is currently subject to the following lawsuits:Â On March 13,2024, a shareholder class action complaint was filed in the United States District Court for the Southern District of New York. The complaintis captioned Blum v. Anavex Life Sciences, Corp. et al., case number 1:24-cv-01910, and it named the Company and Christopher Misslingas Defendants. The complaint alleges violations of the Securities and Exchange Act of 1934 associated with disclosures and statementsmade with respect to certain clinical trials for ANAVEXÂ®2-73 related to Rett syndrome (the â€œMarch 2024 Complaintâ€).At a hearing on or about June 13, 2024, the Court named another purported Company shareholder, Quintessa Huey, as lead plaintiff withrespect to the March 2024 Complaint. An Amended Complaint was filed by the appointed lead plaintiff on July 12, 2024, which asserts allegationsrelated to purported violations of Section 10(b) of the Securities Exchange Act tied to disclosures associated with the same clinicaltrials related to Rett Syndrome, and which names the Company and Christopher Missling as defendants. The Amended Complaint seeks unspecifieddamages, as well as costs, including counsel and expert witness fees, on behalf of class of investors who purchased stock of the Companyon the NASDAQ during the period February 1, 2022 through January 1, 2024.Â The defendants filed a motion to dismiss the complaint.The motion to dismiss is fully-briefed and awaiting a decision by the Court.Â On May 8, 2024,a similar complaint was filed in the same court by Kenneth Downing (case no. 1:2024-cv-03529), a purported shareholder of the Company,against the same defendants as the March 2024 Complaint. The defendants filed a motion to dismiss the complaint. Plaintiff Downing voluntarilydismissed his complaint subsequent to the filing of the motion to dismiss.Â On or aboutMay 13, 2024, a derivative lawsuit was filed against the Company (as nominal defendant), Christopher Missling, and members of the Companyâ€™sBoard of Directors in the U.S. District Court for the District of Nevada by another purported shareholder named Denise Deangelis.Â Thecomplaint asserts various common law claims (including breach of fiduciary duty) and violation of Section 14(a) of the Securities ExchangeAct regarding the same or similar allegations at issue in the two purported class action lawsuits related to disclosures and statementsmade about certain clinical trials related to Rett Syndrome. The parties are currently due to file a proposed schedule for the anticipatedmotion to dismiss by the Company and Christopher Missling (the other named defendants have not been served with the complaint) on or beforeJanuary 15, 2025.Â Weknow of no other material pending legal or governmental proceedings, other than ordinary routine litigation incidental to our business,to which our Company or our subsidiaries are a party or of which any of their property is subject. There are no other proceedings in whichany of our directors, officers or affiliates, or any registered or beneficial stockholder holding more than 5% of our shares, or any associateof such persons, is an adverse party or has a material interest adverse to our or our subsidiariesâ€™ interest.Â 63 Â Â ITEM 4. MINE SAFETY DISCLOSURESÂ Not applicable.Â PART IIÂ ITEM 5. MARKET FOR REGISTRANTâ€™SCOMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIESÂ Market informationÂ Our common stock is quoted on the Nasdaq Global SelectStock Market (â€œNasdaqâ€) under the symbol â€œAVXL.â€Â Holders of Common Stock Â As of December 23, 2024, there were approximately48 stockholders of record, and 84,815,517 shares of our common stock were issued and outstanding. Most of our stockholders hold theirshares in street name.Â Dividends Â We have not paid any cash dividends on our commonstock 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 ourBoard of Directors.Â Recent Sales of Unregistered Securities Â Since the beginning of our fiscal year ended September30, 2024, we have not sold any equity securities that were not registered under the Securities Act of 1933 that were not previously reportedin a quarterly report on Form 10-Q or in a current report on Form 8-K.Â Repurchases of Equity Securities by Our Companyand Affiliated PurchasersÂ None.Â ITEM 6 [Reserved]Â ITEM 7 MANAGEMENTâ€™SDISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONÂ The following discussion should be read in conjunctionwith our consolidated financial statements and related notes thereto included elsewhere in this report. Past operating results are notnecessarily indicative of results that may occur in future periods. This discussion contains forward-looking statements, which involvea number of risks and uncertainties. See Forward Looking Statements included elsewhere in this report.Â Financial Operations OverviewÂ We are inthe development stage and have not earned any revenues since our inception in 2004. We do not anticipate earning any revenues until wecan establish an alliance with other companies to develop, co-develop, license, acquire or market our products.Â 64 Â Â Our operating costs consist primarily of research and developmentactivities including the cost of clinical studies and clinical supplies as well as clinical drug manufacturing and formulation. Researchand development expenses also include personnel related costs such as salaries and wages, and third-party contract research organization(CRO) expenses in support of these clinical studies. Personnel costs include salaries and wages, benefits, and non-cash share-based compensationcharges associated with options and other equity awards granted to employees and consultants who are directly engaged in support of ourresearch and development activities.Â General and administrative expenses consist of personnel costs,expenses for outside professional services and expenses associated with operating as a public company. Personnel costs consist of salariesand wages, benefits and share-based compensation for general and administrative personnel. Outside professional services and public companyexpenses include expenses related to compliance and reporting, additional insurance expenses, audit and SOX compliance, expenses associatedwith patent research, applications and filings, investor and stockholder relations

activities and other administrative expenses and professionalservices.Â Comparison of year ended September 30, 2024 to year endedSeptember 30, 2023Â Operating ExpensesÂ Our operating expenses for fiscal 2024 decreased to $52.9 million,from $55.8 million in fiscal 2023. The decrease is attributable to a modest decrease in research and development expenses of $1.9 million(4.3%) to $41.8 million in fiscal 2024 as well as a small decrease in general and administrative expenses of $1.0 million (8.3%) to $11.0million in fiscal 2024, as more fully described below.Â During fiscal 2024, we experienced an overall decreasein total research and development expenses over the comparable fiscal 2023 financial year.Â The decreases were largely due to:Â (i)a decrease in share-based compensation expense of $5.0 million as a result of the vesting of previousoption awards and a change in estimated vesting dates associated with performance-based option awards;Â (ii)a decrease of approximately $3.5 million relating to our Rett syndrome program as a result of the completionof the EXCELLENCE trial and the respective open label extension; andÂ (iii)a decrease of approximately $1.2 million in expenditures over the comparable period relating to our Alzheimerâ€™sprogram, as a result of the completion of the Phase 2b/3 clinical trial and its related open label extension.Â These decreases were largely offset by the followingincreases in research and development expenditures over the comparable fiscal 2023 financial year:Â (i)an increase in personnel costs of $3.4 million related to the addition of new employees including newadditions to the Companyâ€™s leadership team, and expenses related to the engagement of consultants to assist in the preparation ofthe submission of our Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA);Â (ii)an increase of approximately $3.6 million over the comparable period relating to manufacturing activitiesof ANAVEXÂ®2-73 for potential commercial use, and to support the MAA; andÂ (iii)an increase of $2.2 million over the comparable period relating to expenditures on the ANAVEXÂ®3-71-SZ-001clinical trial, which trial commenced in the second quarter of fiscal 2024.Â 65 Â Â The following table summarizes our research and development expenses forthe years ended September 30, 2024, and 2023 (in thousands): Â Â 2024Â 2023 Costs of external service providersÂ $21,974Â Â $22,542Â Personnel costsÂ Â 13,676Â Â Â 10,264Â Share-based compensationÂ Â 5,813Â Â Â 10,812Â Other common costsÂ Â 375Â Â Â 99Â Total research and development costsÂ $41,838Â Â $43,717Â Â External service provider cost by product candidatewas as follows (in thousands):Â Â Â 2024Â 2023 ANAVEXÂ®2-73Â $17,572Â Â $19,540Â ANAVEXÂ®3-71Â Â 3,748Â Â Â 2,624Â All other product candidatesÂ Â 150Â Â Â 6Â Other external service provider costsÂ Â 504Â Â Â 372Â Total external service provider costsÂ $21,974Â Â $22,542Â Â General and administrative expenses were $11.0 millionfor the fiscal 2024 financial year, as compared to $12.0 million in fiscal 2023. The primary reason for the decrease in general and administrativeexpenses was a reduction in share-based compensation charges of $1.9 million, as a result of the vesting of previous option awards andthe extended timeline of milestone based vesting awards.Â Weexpect to see our research and development expenditures increase from current levels as we advance our clinical programs, including continuationof ANAVEXÂ®3-71 trial in Schizophrenia and subsequent advancements, planned advancement of ANAVEXÂ®2-73 forParkinsonâ€™s disease, planned initiation of an ANAVEXÂ®2-73for a Fragile X clinical trial, and as we continue to grow our staffing to manage and support these clinical initiatives. Â Other income (net)Â Net other income for the year ended September 30, 2024 was $9.9million as compared to $8.3 million for fiscal 2023. The primary reason for the increase in other income was due to a one-time financingcharge of $0.9 million recognized in the comparable year associated with entering into the 2023 Purchase Agreement (as described below),as well as an increase in interest income in fiscal 2024 earned on cash and cash equivalents, due to an increase in market wide interestrates year over year.Â Duringfiscal 2024, we recorded $2.3 million in research and development incentive income, consisting of the Australian research and developmentincentive credit administered through the ATO, in connection with fiscal 2024 eligible expenditures. In comparison, research and developmentincentive income for fiscal 2023 was $2.7 million in connection with fiscal 2023 eligible expenditures. This income is driven by the clinicaltrial expenditures incurred in Australia, and the decrease is a result of the completion of the EXCELLENCE trial in Rett Syndrome andthe Phase 2b/3 clinical trial in Alzheimerâ€™s disease, as well asrelated open label extension trials, which were completed during fiscal 2024. We expect to continue to receive support from the Australiangovernment for future clinical trials which we plan to conduct, in part, within Australia. Â Net lossÂ Net loss for fiscal 2024 was $43.0 million, or $0.52per share, compared to a net loss of approximately $47.5 million, or $0.60 per share for fiscal 2023.Â 66 Â Â Liquidity and Capital Resources Â Working Capital (in thousands)Â Â Â 2024Â 2023 Current AssetsÂ $135,567Â Â $154,386Â Current LiabilitiesÂ Â 15,304Â Â Â 12,534Â Working CapitalÂ $120,263Â Â $141,852Â Â At September 30, 2024, we had $132.2 million in cash and cashequivalents, a decrease from $151.0 million at September 30, 2023.Â We intend to continue to use our capital resources to advanceour clinical trials for ANAVEXÂ®2-73 and ANAVEXÂ®3-71, and to perform work necessary to prepare for futuredevelopment of our pipeline compounds.Â Cash Flows Â Following is a summaryof sources of cash flows for the years ended September 30, 2024 and 2023 (in thousands)Â Â Â 2024Â 2023 Cash flows used in operating activitiesÂ $(30,812)Â $(27,785) Cash flows provided by financing activitiesÂ Â 11,975Â Â Â 29,651Â (Decrease) increase in cashÂ $(18,837)Â $1,866Â Â Cash flow used in operating activitiesÂ There was an increase in cash used in operating activities of$3.0 million during fiscal 2024. The principal reason for this is an increase in net cash expenses, after taking into account non-cashshare-based compensation, over the comparable period of approximately $3.3 million.Â Cash flow provided by financing activitiesÂ Cash provided by financing activities in fiscal 2024 was $12.0million, comprised of $11.3 attributable to cash received from the issuance of common shares at various market prices under the 2023 PurchaseAgreement (as defined below) and $0.7 million received pursuant to the exercise of stock options.Â Cash provided by financing activities in fiscal 2023 was $29.7million, comprised of $27.9 million attributable to cash received from the issuance of common shares under the 2023 Purchase Agreementand $1.8 million received pursuant to the exercise of stock options.Â Other FinancingsÂ 2023 Purchase AgreementÂ On February 3, 2023, the Company entered into a $150,000,000purchase agreement (the â€œ2023 Purchase Agreementâ€) with Lincoln Park Capital Fund, LLC (â€œLincoln Parkâ€), pursuantto which the Company has the right to sell and issue to Lincoln Park, and Lincoln Park is obligated to purchase, up to $150.0 millionin value of its shares of Common Stock from time to time over a three-year period until February 3, 2026.Â 67 Â Â On any business day and subject to certain customaryconditions, the Company may direct Lincoln Park to purchase up to 200,000 shares of Common Stock (such purchases, â€œRegular Purchasesâ€).The amount of a Regular Purchase may increase under certain circumstances based on the market price of the Common Stock; provided, however,that Lincoln Parkâ€™s committed obligation under any Regular Purchase shall not exceed $4.0 million. The purchase price of sharesof Common Stock will be based on the then prevailing market prices of such shares at the time of sales as described in the 2023 PurchaseAgreement. There are no limits on the price per share that Lincoln Park may pay to purchase Common Stock under the 2023 Purchase Agreement.In addition, if the Company has directed Lincoln Park to purchase the full amount of Common Stock available as a Regular Purchase on agiven day, it may direct Lincoln Park to purchase additional amounts as

â€œaccelerated purchasesâ€ and â€œadditional acceleratedpurchases,â€ each as set forth in the 2023 Purchase Agreement.Â The 2023 Purchase Agreement limits the Companyâ€™ssale of shares of Common Stock to Lincoln Park to 15,606,426 shares of Common Stock, representing 19.99% of the shares of the Common Stockoutstanding on the date of the 2023 Purchase Agreement unless (i) stockholder 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 2023 Purchase Agreement equals or exceeds the lowerof (A) the closing price of the Common Stock on the Nasdaq Capital Market immediately preceding the Execution Date or (B) the averageof the closing price of the Common Stock on the Nasdaq Capital Market for the five Business Days immediately preceding the Execution Date.Â The 2023 Purchase Agreement also prohibits the Companyfrom directing Lincoln Park to purchase any shares of Common Stock if those shares, when aggregated with all other shares of Common Stockthen beneficially owned by Lincoln Park and its affiliates, would result in Lincoln Park and its affiliates having beneficial ownership,at any single point in time, of more than 4.99% of the then total outstanding shares of Common Stock, as calculated pursuant to Section13(d) of the Securities Exchange Act of 1934, as amended, and Rule 13d-3 thereunder.Â In consideration for entering into the 2023 PurchaseAgreement, the Company issued to Lincoln Park 75,000 shares of Common Stock as a commitment fee (the â€œinitial commitment sharesâ€)during the year ended September 30, 2023 and agreed to issue up to 75,000 shares pro rata (collectively with the initial commitment shares,the â€œcommitment sharesâ€), when and if, Lincoln Park purchased, at the Companyâ€™s discretion, the $150.0 million aggregatecommitment.Â During the year ended September 30, 2024, the Companyissued to Lincoln Park an aggregate of 2,455,646 shares of Common Stock under the 2023 Purchase Agreement, including 2,450,000 sharesof Common Stock for an aggregate purchase price of $11.3 million and 5,646 commitment shares. During the year ended September 30, 2023,the Company issued to Lincoln Park an aggregate of 3,288,943 shares of Common Stock under the 2023 Purchase Agreement, including 3,275,000shares of Common Stock for an aggregate purchase price of $27.9 million and 13,943 commitment shares as well as the 75,000 initial commitmentshares.Â On September 30, 2024, an amount of $110.8 millionremained available under the 2023 Purchase Agreement.Â Controlled Equity Offering Sales AgreementÂ On May 1, 2020, we entered into an Amended and RestatedSales Agreement (the â€œ2020 Sales Agreementâ€) with Cantor Fitzgerald & Co. and SVB Leerink LLC (the â€œSales Agentsâ€),pursuant to which we could offer and sell shares of Common Stock registered under an effective registration statement from time to timethrough the Sales Agents (the â€œAt-the-Market Offeringâ€).Â No shares were sold during the years ended September30, 2024 and 2023 under the 2020 Sales Agreement. The Company terminated the 2020 Sales Agreement on July 24, 2024.Â Off-Balance Sheet ArrangementsÂ We have no off-balance sheet arrangements that haveor 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.Â 68 Â Â Applicationof Critical Accounting PoliciesÂ Ourfinancial 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 managementâ€™sapplication of accounting policies. We believe that understanding the basis and nature of the estimates and assumptions involved withthe following aspects of our financial statements is critical to an understanding of our financial statements.Â We base our assumptions and estimates on historical experienceand 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 warrantsand options.Â There are accounting policies that we believe are significantto the presentation of our financial statements. The most significant of these accounting policies relates to the accounting for our researchand development expenses and share-based compensation expense.Â Research and Development ExpensesÂ Researchand development costs are expensed as incurred. These expenses are comprised of the costs of the Companyâ€™sproprietary research and development efforts, including preclinical studies, clinical trials, manufacturing costs, employee salaries andbenefits and share-based compensation expense, contract services including external research and development expenses incurred under arrangementswith third parties such as contract research organizations (â€œCROsâ€),facilities costs, overhead costs and other related expenses. Milestone payments made by the Company to third parties are expensed whenthe specific milestone has been achieved. Manufacturing costs are expensed as incurred in accordance with Accounting Standard Codification(â€œASCâ€)730, Research and Development, as these materials have no alternative future use outside of their intended use.Â Nonrefundable advance payments for goods or services that willbe 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 relationto 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. TheCompany reviews and accrues CRO expenses and clinical trial study expenses based on work performed and relies upon estimates of thosecosts 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 clinicalsite costs, the financial terms of these agreements are subject to negotiation and vary from contract to contract. Payments under thesecontracts may be uneven and depend on factors such as the achievement of certain events, the successful recruitment of patients, the completionof portions of the clinical trial or similar conditions. The objective of our policy is to record expenses in our financial statementsbased on actual services received and efforts expended. As such, expense accruals related to clinical site costs are recognized basedon our estimate of the degree of completion of the event or events specified in the specific clinical trial contract.Â In addition, we incur expenses in respect of the acquisitionof intellectual property relating to patents and trademarks. The probability of success and length of time to develop commercial applicationsof the drugs subject to the acquired patents and trademarks is difficult to determine and numerous risks and uncertainties exist withrespect to the timely completion of the development projects. There is no assurance the acquired patents and trademarks will ever be successfullycommercialized. Due to these risks and uncertainties, we expense the acquisition of patents and trademarks. 69 Â Â Share-based CompensationÂ We account for all share-based payments and awards under thefair value-based method.Â The fair value of all share purchase options and warrants areexpensed 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.Â Compensation costs

for share-based payments with graded vestingare recognized on a straight-line basis. Share-based compensation expense is adjusted for actual forfeitures of unvested awards as theyoccur.Â We have granted share purchase option awards that vest uponachievement of certain performance criteria, or milestone-based awards. We estimate an implicit service period for achieving performancecriteria for each award and recognizes the resulting fair value as expense over the implicit service period when we conclude that achievingthe performance criteria is probable. We periodically review and update as appropriate our estimates of implicit service periods and conclusionson achieving the performance criteria. Performance awards vest upon achievement of the performance criteria.Â Weuse the Black-Scholes option valuation model to calculate the fair value of share purchase options and warrants at the date of the grant.This model requires the input of subjective assumptions, including the expected price volatility, and expected life of eachÂ award.These assumptions consist of estimates of future market conditions, which are inherently uncertain, and therefore, are subject to managementâ€™sjudgment. Changes in these assumptions can materially affect the fair value estimates.Â RECENT ACCOUNTING PRONOUNCEMENTSÂ For a discussion of recent accounting pronouncements and theirpossible effect on our results, see Note 2 to our Consolidated Financial Statements found elsewhere in this Annual Report.Â ITEM 7A QUANTITATIVE AND QUALITATIVEDISCLOSURES ABOUT MARKET RISKÂ Not required for smaller reporting companies.Â 70 Â Â ITEM 8. FINANCIAL STATEMENTSAND SUPPLEMENTARY DATAÂ ANAVEX LIFE SCIENCES CORP.CONSOLIDATED FINANCIAL STATEMENTSSeptember 30, 2024Â F-1 Â Â REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRMÂ Board of Directors and ShareholdersÂ Anavex Life Sciences Corp.Â Opinion on the financial statements Â We have audited the accompanying consolidated balance sheets of AnavexLife Sciences Corp. (a Nevada corporation) and subsidiaries (the â€œCompanyâ€) as of September 30, 2024 and 2023, the relatedconsolidated statements of operations and comprehensive loss, changes in stockholdersâ€™ equity, and cash flows for each of the twoyears in the period ended September 30, 2024, and the related notes (collectively referred to as the â€œfinancial statementsâ€).In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of September30, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended September 30, 2024,in conformity with accounting principles generally accepted in the United States of America.Â Basis for opinion Â These financial statements are the responsibility of the Companyâ€™smanagement. Our responsibility is to express an opinion on the Companyâ€™s financial statements based on our audits. We are a publicaccounting firm registered with the Public Company Accounting Oversight Board (United States) (â€œPCAOBâ€) and are required tobe independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulationsof the Securities and Exchange Commission and the PCAOB.Â 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 financial statements are freeof material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an auditof its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal controlover financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Companyâ€™s internal controlover financial reporting. Accordingly, we express no such opinion.Â Our audits included performing procedures to assess the risks of materialmisstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such proceduresincluded examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also includedevaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentationof the financial statements. We believe that our audits provide a reasonable basis for our opinion.Â Critical audit mattersÂ Critical audit matters are matters arising from the current period auditof the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accountsor disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments.We determined that there are no critical audit matters.Â /s/ GRANT THORNTON LLPÂ We have served as the Companyâ€™s auditor since 2022.Â Melville, New YorkDecember 23, 2024Â 248 F-2 Â Â Â Â Â Â Â Â Â Â Â Anavex Life Sciences Corp. Consolidated Balance Sheets (in thousands, except share and per share amounts) Â Â Â Â Â Â Â September 30, Â Â 2024Â 2023 Â Â Â Â Â AssetsÂ Â Â Â Â Â Â Â CurrentÂ Â Â Â Â Â Â Â Cash and cash equivalentsÂ $132,187Â Â $151,024Â Incentive and tax receivablesÂ Â 2,449Â Â Â 2,709Â Prepaid expenses and other current assetsÂ Â 931Â Â Â 653Â Total AssetsÂ $135,567Â Â $154,386Â Â Â Â Â Â Â Â Â Â Liabilities and Stockholdersâ€™ EquityÂ Â Â Â Â Â Â Â Current LiabilitiesÂ Â Â Â Â Â Â Â Accounts payableÂ $9,627Â Â $4,322Â Accrued liabilities - Note 3Â Â 4,835Â Â Â 7,295Â Deferred grant income - Note 4Â Â 842Â Â Â 917Â Total LiabilitiesÂ $15,304Â Â $12,534Â Â Â Â Â Â Â Â Â Â Commitments and Contingencies - Note 6Â Â â€"Â Â Â â€"Â Â Â Â Â Â Â Â Â Â Capital stockÂ Â Â Â Â Â Â Â Authorized:Â Â Â Â Â Â Â Â 10,000,000 preferred stock, par value $0.001 per shareÂ Â â€"Â Â Â â€"Â 200,000,000 common stock, par value $0.001 per shareÂ Â Â Â Â Â Â Â Issued and outstanding:Â Â Â Â Â Â Â Â 84,795,517 common shares (2023 - 82,066,511)Â Â 85Â Â Â 82Â Additional paid-in capitalÂ Â 456,249Â Â Â 434,839Â Accumulated deficitÂ Â (336,071)Â Â (293,069) Total Stockholdersâ€™ EquityÂ $120,263Â Â $141,852Â Total Liabilities and Stockholdersâ€™ EquityÂ $135,567Â Â $154,386Â Â SeeAccompanying Notes to Consolidated Financial StatementsÂ F-3 Â Â Â Â Â Â Â Â Â Â Â Anavex Life Sciences Corp. Consolidated Statements of Operations and Comprehensive Loss (in thousands, except share and per share amounts) Â Â Â Â Â Â Â Years Ended September 30, Â Â 2024Â 2023 Operating expensesÂ Â Â Â Â Â Â Â General and administrativeÂ $11,039Â Â $12,039Â Research and developmentÂ Â 41,838Â Â Â 43,717Â Â Â Â Â Â Â Â Â Â Total operating expensesÂ Â 52,877Â Â Â 55,756Â Operating lossÂ Â (52,877)Â Â (55,756) Â Â Â Â Â Â Â Â Â Other income (expense)Â Â Â Â Â Â Â Â Grant incomeÂ Â 75Â Â Â 25Â Research and development incentive incomeÂ Â 2,291Â Â Â 2,718Â Interest income, netÂ Â 7,320Â Â Â 6,519Â Other financing expenseÂ Â â€"Â Â Â (964) Foreign exchange gain (loss)Â Â 189Â Â Â (40) Â Â Â Â Â Â Â Â Â Total other income, netÂ Â 9,875Â Â Â 8,258Â Net loss before provision for income taxesÂ Â (43,002)Â Â (47,498) Â Â Â Â Â Â Â Â Â Income tax expense, currentÂ Â â€"Â Â Â (7) Â Â Â Â Â Â Â Â Â Net loss and comprehensive lossÂ $(43,002)Â $(47,505) Â Â Â Â Â Â Â Â Â Net Loss per shareÂ Â Â Â Â Â Â Â Basic and dilutedÂ $(0.52)Â $(0.60) Â Â Â Â Â Â Â Â Â Weighted average number of shares outstandingÂ Â Â Â Â Â Â Â Basic and dilutedÂ Â 83,468,049Â Â Â 79,787,596Â Â SeeAccompanying Notes to Consolidated Financial StatementsÂ F-4 Â Â Â Â Â Â Â Â Â Â Â Anavex Life Sciences Corp. Consolidated Statements of Cash Flows (in thousands, except share and per share amounts) Â Â Â Â Â Â Â Years ended September 30, Â Â 2024Â 2023 Â Â Â Â Â Cash Flows used in Operating ActivitiesÂ Â Â Â Â Â Â Â Net lossÂ $(43,002)Â $(47,505) Adjustments to reconcile net loss to net cash used in operations:Â Â Â Â Â Â Â Â Non-cash financing related chargesÂ Â â€"Â Â Â 845Â Share-based compensationÂ Â 9,438Â Â Â 16,370Â Changes in working capital balances related to operations:Â Â Â Â Â Â Â Â

Incentive and tax receivablesÂ Â 260Â Â Â 484Â Prepaid expenses and depositsÂ Â (278)Â Â (299) Accounts payableÂ Â 5,305Â Â Â 497Â Accrued liabilitiesÂ Â (2,460)Â Â 1,350Â Deferred grant incomeÂ Â (75)Â Â 473Â Net cash used in operating activitiesÂ Â (30,812)Â Â (27,785) Â Â Â Â Â Â Â Â Â Cash Flows provided by Financing ActivitiesÂ Â Â Â Â Â Â Â Issuance of common sharesÂ Â 11,284Â Â Â 27,875Â Proceeds from exercise of stock optionsÂ Â 691Â Â Â 1,776Â Net cash provided by financing activitiesÂ Â 11,975Â Â Â 29,651Â Â Â Â Â Â Â Â Â Â (Decrease) Increase in cash and cash equivalents during the yearÂ Â (18,837)Â Â 1,866Â Cash and cash equivalents, beginning of yearÂ Â 151,024Â Â Â 149,158Â Cash and cash equivalents, end of yearÂ $132,187Â Â $151,024Â Â Â Â Â Â Â Â Â Â Supplemental Cash Flow InformationÂ Â Â Â Â Â Â Â Cash paid for state and local franchise taxesÂ $300Â Â $136Â Â SeeAccompanying Notes to Consolidated Financial StatementsÂ F-5 Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Anavex Life Sciences Corp. Consolidated Statements of Changes in Stockholdersâ€™ Equity (in thousands, except share and per share amounts) Â Â Â Â Â Â Â Â Â Â Â Â Â Common StockÂ Additional Paid-inÂ AccumulatedÂ Â Â Â SharesÂ Par ValueÂ CapitalÂ DeficitÂ Total Â Â Â Â Â Â Â Â Â Â Â Balance, October 1, 2022Â Â 77,942,815Â Â $78Â Â $387,977Â Â $(245,564)Â $142,491Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Shares issued under 2023 Purchase AgreementÂ Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Initial Commitment sharesÂ Â 75,000Â Â Â â€"Â Â Â 845Â Â Â â€"Â Â Â 845Â Â Purchase sharesÂ Â 3,275,000Â Â Â 3Â Â Â 27,872Â Â Â â€"Â Â Â 27,875Â Â Commitment sharesÂ Â 13,943Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Shares issued pursuant to exercise of stock optionsÂ Â 759,753Â Â Â 1Â Â Â 1,775Â Â Â â€"Â Â Â 1,776Â Share based compensationÂ Â â€"Â Â Â â€"Â Â Â 16,370Â Â Â â€"Â Â Â 16,370Â Net lossÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â (47,505)Â Â (47,505) Balance, September 30, 2023Â Â 82,066,511Â Â Â 82Â Â Â 434,839Â Â Â (293,069)Â Â 141,852Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Shares issued under 2023 Purchase AgreementÂ Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Purchase sharesÂ Â 2,450,000Â Â Â 3Â Â Â 11,281Â Â Â â€"Â Â Â 11,284Â Â Commitment sharesÂ Â 5,646Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Shares issued pursuant to exercise of stock optionsÂ Â 273,360Â Â Â â€"Â Â Â 691Â Â Â â€"Â Â Â 691Â Share based compensationÂ Â â€"Â Â Â â€"Â Â Â 9,438Â Â Â â€"Â Â Â 9,438Â Net lossÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â (43,002)Â Â (43,002) Balance, September 30, 2024Â Â 84,795,517Â Â $85Â Â $456,249Â Â $(336,071)Â $120,263Â Â SeeAccompanying Notes to Consolidated Financial StatementsÂ F-6 Â Â AnavexLife Sciences Corp.Notesto the Consolidated Financial StatementsSeptember30, 2024 â€" Page 7Â Note 1 Business Description and Basis of PresentationÂ BusinessÂ Anavex Life Sciences Corp. (â€œAnavexâ€ orthe â€œCompanyâ€) is a clinical stage biopharmaceutical company engaged in the development of differentiated therapeutics byapplying precision medicine to central nervous system (â€œCNSâ€) diseases with high unmet need. Anavex analyzes genomic datafrom clinical trials to identify biomarkers, which are used in the analysis of its clinical trials for the treatment of neurodegenerativeand neurodevelopmental diseases.Â The Companyâ€™s focus is on developing innovativetreatments for Alzheimerâ€™s disease, Parkinsonâ€™s disease, schizophrenia, neurodevelopmental, neurodegenerative, and rare diseases,including Rett syndrome, and other central nervous system (CNS) disorders.Â Basis of PresentationÂ These consolidated financial statements have beenprepared pursuant to the rules and regulations of the Securities and Exchange Commission (â€œSECâ€) and the instructions to Form10-K and have been prepared under the accounting principles generally accepted in the United States of America (â€œU.S. GAAPâ€).Â LiquidityÂ All of the Companyâ€™s potential drug compoundsare 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 revenue from our operations. The Company expects the business to continue to experience negative cashflows from operations for the foreseeable future and cannot predict when, if ever, our business might become profitable.Â Management believes that the current working capitalposition will be sufficient to meet the Companyâ€™s working capital requirements beyond the next 12 months after the date that theseconsolidated financial statements are issued. The process of drug development can be costly, and the timing and outcomes of clinical trialsare uncertain.Â The assumptions upon which the Company has based its estimates are routinely evaluated and may be subject to change.Â Theactual amount of the Companyâ€™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 Companyâ€™s research and development programs and the level offinancial resources available. The Company has the ability to adjust its operating plan spending levels based on the timing of futureclinical trials.Â Other than our rights related to the 2023 PurchaseAgreement (as defined below in Note 5), there can be no assurance that additional financing will be available to us when needed or, ifavailable, that it can be obtained on commercially reasonable terms. If the Company is not able to obtain the additional financing ona 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.Â Note 2 Summary of Significant Accounting Policies Â Use of EstimatesÂ The preparation of financial statements in accordancewith U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at thedate of the financial statements and the reported amounts of revenue and expenses in the reporting period. The Company regularly evaluatesestimates and assumptions related to accounting for research and development costs, incentive and tax receivables, valuation and recoverabilityof deferred tax assets, 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 formthe basis for making judgments about the carrying values of assets and liabilities and the accrual of costs and expenses that are notreadily apparent from other sources. The actual results experienced by the Company may differ materially and adversely from the Companyâ€™sestimates. To the extent there are material differences between the estimates and the actual results, future results of operations willbe affected.Â F-7 Â Â AnavexLife Sciences Corp.Notesto the Consolidated Financial StatementsSeptember30, 2024 â€" Page 8Â Principles of ConsolidationÂ These consolidated financial statements include theaccounts of Anavex Life Sciences Corp. and its wholly-owned subsidiaries, Anavex Australia Pty Limited (â€œAnavex Australiaâ€),a company incorporated under the laws of Australia, Anavex Germany GmbH, a company incorporated under the laws of Germany, and AnavexCanada Ltd., a company incorporated under the laws of the Province of Ontario, Canada. All inter-company transactions and balances havebeen eliminated.Â Cash and equivalentsÂ The Company considers onlythose investments which are highly liquid, readily convertible to cash and that mature within three months from the date of purchase tobe cash equivalents.Â Highlyliquid investments that are considered cash equivalents include money marketÂ accounts, money marketÂ fundsÂ andÂ certificatesof deposit. The carrying value of cash equivalents approximates fair value due to the short-term maturity of these securities. The Companyâ€™sinvestment policy allows for investments in domestic money market certificates, certificates of deposit, money market funds, bonds orcommercial papers, and establishes

diversification and credit quality requirements and limits investments by maturity and issuer. TheCompany currently maintains its investments at one large well known financial institution.Â TheCompany maintains its cash in bank deposit accounts which, at times, may exceed federally insured limits. Accounts are guaranteed by theFederal Deposit Insurance Corporation (FDIC) up to $250,000, under current regulations. At September 30, 2024 and 2023, substantiallyall of the Companyâ€™s cash balances were in excess of these federally insured limits. The Company mitigates this risk by maintainingthe majority of its cash balances in a large well-known financial institution. The Company has not experienced any losses in such accounts.Â Research and Development ExpensesÂ Research and development costs are expensed as incurred.These expenses are comprised of the costs of the Companyâ€™s proprietary research and development efforts, including preclinical studies,clinical trials, manufacturing costs, employee salaries and benefits and share-based compensation expense, contract services includingexternal research and development expenses incurred under arrangements with third parties such as contract research organizations (â€œCROsâ€),facilities costs, overhead costs and other related expenses. Milestone payments made by the Company to third parties are expensed whenthe specific milestone has been achieved. Manufacturing costs are expensed as incurred in accordance with Accounting Standard Codification(â€œASCâ€) 730, Research and Development, as these materials have no alternative future use outside of their intendeduse.Â Nonrefundable advance payments for goods or servicesthat will be used or rendered for future research and development activities are deferred and amortized over the period that the goodsare delivered, or the related services are performed, subject to an assessment of recoverability. The Company makes estimates of costsincurred in relation to external CROs, and clinical site costs. When evaluating the adequacy of the accrued liabilities, the Company analyzesprogress of the trials and studies including the phase or completion of events, invoices received and contracted costs. Judgments andestimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Companyâ€™sestimates. The Companyâ€™s historical accrual estimates have not been materially different from actual costs.Â In addition, the Company incurs expenses in respectof intellectual property costs relating to patents and trademarks. The probability of success and length of time to develop commercialapplications of the drugs subject to the underlying patent and trademark costs is difficult to determine and numerous risks and uncertaintiesexist with respect to the timely completion of the development projects. There is no assurance the drugs subject to the underlying patentsand trademarks will ever be successfully commercialized.Â F-8 Â Â AnavexLife Sciences Corp.Notesto the Consolidated Financial StatementsSeptember30, 2024 â€“ Page 9Â Due to these risks and uncertainties, the patent andtrademark costs do not meet the definition of an asset and thus are expensed as incurred within general and administrative expenses.Â Research and Development Incentive IncomeÂ The Company is eligible to obtain certain researchand development tax credits, including, through its wholly owned subsidiary Anavex Australia, the Australian research and developmenttax incentive credit (the â€œAustralia R&D creditâ€) through a program administered through the Australian Tax Office (theâ€œATOâ€) and AusIndustry, a division of the Australian Governmentâ€™s Department of Industry, Innovation and Science (â€œAusIndustryâ€).The Australia R&D credit program provides for a cash refund based on a percentage of eligible research and development activitiesundertaken in Australia by Anavex Australia. Anavex Australia is also eligible under the Australia R&D credit program to receive thecash refund for certain research and development expenses incurred by Anavex Australia outside of Australia, to the extent such expensesare pre-approved by AusIndustry pursuant to an advanced overseas finding application.Â The Australia R&D credit program is availableto eligible companies with an annual aggregate revenue of less than $20.0 million Australian during the reimbursable period at a rateof 18.5% above the claimantâ€™s company tax rate in Australia.Â The tax incentives are available on the basis of specificcriteria with which the Company must comply. Although the tax incentive may be administered through the local tax authority, the Companyhas accounted for the incentives outside of the scope of ASC Topic 740, Income Taxes (â€œASC 740â€), since the incentivesare not linked to the Companyâ€™s taxable income and can be realized regardless of whether the Company has generated taxable incomein the respective jurisdictions.Â With respect to the Australia R&D credit, as thereis no authoritative guidance under GAAP for accounting for grants to for-profit business entities, the Company accounts for the grantby analogy to IAS20 Accounting for Government Grants and Disclosure of Government Assistance (â€œIAS 20â€). The Companyrecognizes the research and development incentive income as it incurs costs eligible for reimbursement under the Australia R&D creditprogram when it is reasonably assured that the cash incentive will be received, as evidenced through enrollment in the program and whenthe applicable conditions under the program have been met. The Company accrues for the amount of cash refund it expects to receive inrelation to research and development expenses outside of Australia only to the extent it has received advanced approval from AusIndustry,pursuant to an approved advanced overseas finding application.Â In addition, Anavex Australia and Anavex Canada incurGoods and Services Tax (GST) on certain services provided by local vendors. As a domestic entity in those jurisdictions, Anavex Australiaand Anavex Canada are entitled to a refund of the GST paid. Similarly, Anavex Germany incurs Value Added Tax (VAT) on certain servicesprovided by local vendors, to which it is entitled to a refund of such VAT paid. The Companyâ€™s estimate of the amount of cash refundit expects to receive related to GST and VAT incurred is included in Incentive and tax receivables in the accompanying consolidated balancesheets.Â License FeesÂ TheCompany expenses amounts paid to acquire licenses associated with products under development when the ultimate recovery of the amountspaid is uncertain and the technology has no alternative future use when acquired. Acquisitions of technology licenses are charged to expenseor capitalized based on managementâ€™s assessment regarding the ultimate recoverability of the amounts paid and the potential foralternative future use. The Company has determined that the technological feasibility for its product candidates is reached when the requisiteregulatory approvals are obtained to make the product available for sale.Â F-9 Â Â AnavexLife Sciences Corp.Notesto the Consolidated Financial StatementsSeptember30, 2024 â€“ Page 10Â Basic and Diluted Loss per ShareÂ Basic income/(loss) per common share is computed bydividing 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) theweighted-average number of common shares outstanding during the period, (2) the dilutive effect of the assumed exercise of options andwarrants using the treasury stock method and (3) the dilutive effect of other potentially dilutive securities. For purposes of the dilutednet loss per share calculation, options and warrants are potentially dilutive securities and are excluded from the calculation of dilutednet loss per share because their effect would be anti-dilutive.Â As of September 30, 2024, diluted loss per share excludes15,047,754 potentially dilutive common shares (2023 â€“ 14,271,780) related to outstanding options and warrants, as their effect wasanti-dilutive.Â Financial InstrumentsÂ The book value of the Companyâ€™s financial instruments,consisting of cash and equivalents, incentive and tax receivables, accounts payable and accrued liabilities approximate their fair valuedue to the short-term maturity

of such instruments. Unless otherwise noted, it is managementâ€™s opinion that the Company is not exposedto significant interest, currency or credit risks arising from these financial instruments.Â Foreign Currency TranslationÂ 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 dateand non-monetary items are translated at exchange rates prevailing when the assets were acquired, or obligations incurred. Foreign currencydenominated expense items are translated at exchange rates prevailing on the transaction date. Unrealized gains or losses arising fromthe translations are credited or charged to income in the period in which they occur.Â The Company has determined that the functional currencyof Anavex Australia Pty Limited, Anavex Germany GmbH, and Anavex Canada Ltd. is also the US dollar.Â Segment and Geographic ReportingÂ Operating segments are defined as components of anenterprise for which separate discrete information is available for evaluation by the chief operating decision maker or decision-makinggroup, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business asone operating segment, which is the business of developing novel therapies for the management of CNS diseases.Â Grant IncomeÂ Grant income is recognized at the fair value of thegrant when it is received, and all substantive conditions have been satisfied. Grants received from government and other agencies in advanceof the specific research and development costs to which they relate are deferred and recognized in the consolidated statements of operationsand comprehensive loss in the period they are earned, typically when the related research and development costs are incurred.Â Income TaxesÂ The Company follows the provisions of ASC 740, whichrequires the asset and liability method of accounting for income taxes. Under the asset and liability method, deferred tax assets andliabilities are recognized for the future tax consequences attributable to temporary differences between the financial statements carryingamounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enactedtax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.Â F-10 Â Â AnavexLife Sciences Corp.Notesto the Consolidated Financial StatementsSeptember30, 2024 â€“ Page 11Â The Company follows the provisions of ASC 740 regardingaccounting for uncertainty in income taxes. The Company initially recognizes tax positions in the financial statements when it is morelikely than not the position will be sustained upon examination by the tax authorities. Such tax positions are initially and subsequentlymeasured as the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement with the taxauthority 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 positionsand tax benefits may not accurately anticipate actual outcomes. As additional information is obtained, there may be a need to periodicallyadjust the recognized tax positions and tax benefits. These periodic adjustments may have a material impact on the consolidated statementsof operations and comprehensive loss.Â The Company recognizes interest and penalties relatedto current income tax expense on the interest income, net line, in the accompanying consolidated statements of operations and comprehensiveloss. Accrued interest and penalties, if any, are included in accrued liabilities on the consolidated balance sheets.Â Share-based CompensationÂ The Company accounts for all share-based paymentsand awards under the fair value method.Â The fair value of all share-based payments are expensedover their contractual vesting period, or over the expected performance period for only the portion of awards expected to vest, in thecase of milestone-based vesting, with a corresponding increase to additional paid-in capital.Â Compensation costs for share-based payments with gradedvesting are recognized on a straight-line basis. Stock based compensation expense is adjusted for actual forfeitures of unvested awardsas they occur.Â The Company has granted share purchase option awardsthat vest upon achievement of certain performance criteria, or milestone-based awards. The Company estimates an implicit service periodfor achieving performance criteria for each award and recognizes the resulting fair value as expense over the implicit service periodwhen it concludes that achieving the performance criteria is probable. The Company periodically reviews and updates as appropriate itsestimates of implicit service periods and conclusions on achieving the performance criteria. Performance awards vest upon achievementof the performance criteria.Â The Company uses the Black-Scholes option valuationmodel to calculate the fair value of share-based awards at the date of the grant. This model requires the input of subjective assumptions,including the expected price volatility and expected life of eachÂ award. The Company uses the U.S. Treasury daily treasury yieldcurve rates for the expected term of the option as the risk-free rate. The expected term represents the period that options granted areexpected to be outstanding using the simplified method. The Companyâ€™s historical share option exercise experience does not providesufficient basis for estimating the expected term. Expected volatility is based on the average of the daily share price changes over theexpected term. The Company does not estimate forfeitures and elects to record actual forfeitures as they occur. The Company has not paidany dividends on its common stock historically, therefore no assumption of dividend payments is made in the model. These assumptions consistof estimates of future market conditions, which are inherently uncertain, and therefore, are subject to managementâ€™s judgment. Changesin these assumptions can materially affect the fair value estimates.Â The purchase price of share-based compensation awardsmay be paid in cash or, if approved by the Companyâ€™s compensation committee (or in the case of warrants by the Board of Directors)in advance, â€œnet settledâ€ in shares of the Companyâ€™s common stock. In a net settlement of an share-based award, theCompany does not receive payment of the exercise price from the holder but reduces the number of shares of common stock issued upon theexercise of the award by the smallest number of whole shares that have an aggregate fair market value equal to or over the aggregate exerciseprice for the option shares covered by the instrument exercised. Shares issued pursuant to the exercise of options and warrants are issuedfrom the Companyâ€™s treasury.Â F-11 Â Â AnavexLife Sciences Corp.Notesto the Consolidated Financial StatementsSeptember30, 2024 â€“ Page 12Â Fair Value MeasurementsÂ Fair value is defined as the exchange price that wouldbe received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset orliability in an orderly transaction between market participants at the measurement date. Assets and liabilities that are measured at fairvalue are reported using a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizesthe use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are asfollows:Â Level 1 - quoted prices (unadjusted) in activemarkets for identical assets or liabilities that the Company has the ability to access at the measurement date;Â Level 2 - observable inputs other than Level 1, quotedprices for similar assets or liabilities in active markets, quoted prices for identical or similar assets and liabilities in marketsthat are not active, and model-derived prices whose inputs are observable or whose significant value drivers are observable; andÂ Level 3 - assets and liabilities whose significantvalue drivers are unobservable by little or no market activity and that are significant to the fair value of the assets or liabilities.Â At September 30, 2024 and 2023, the Company did nothave any Level 2 or Level 3

assets or liabilities.Â Recently Adopted Accounting PronouncementsÂ On October 1, 2022, the Companyadopted Accounting Standards Update (ASU) 2021-10, Government Assistance (Topic 832) â€“ Disclosures by Business Entities about GovernmentAssistance, which requires business entities to disclose information about transactions with a government that are accounted for by applyinga grant or contribution model by analogy. For transactions within scope, the new standard requires the disclosure of information aboutthe nature of the transaction, including significant terms and conditions, as well as the amounts and specific financial statement lineitems affected by the transaction. The disclosure of the Companyâ€™s research and development tax incentive income and receivableis detailed in Note 4.Â Recent Accounting PronouncementsÂ In November 2023, the FinancialAccounting Standards Board (FASB) issued ASU No. 2023-07, â€œSegment Reporting: Improvements to Reportable Segment Disclosures.â€This guidance requires disclosure of incremental segment information on an annual and interim basis. This amendment is effective for ourfiscal year ending September 30, 2025 and our interim periods within the fiscal year ending September 30, 2026. The Company is currentlyassessing the impact of this guidance on its disclosures.Â In December 2023, the FASBissued ASU No. 2023-09, â€œIncome Taxes:Â Improvements to Income Tax Disclosures.â€ This guidance requires consistent categoriesand greater disaggregation of information in the rate reconciliation and disclosures of income taxes paid by jurisdiction. This amendmentis effective for our fiscal year ending September 30, 2026. The Company is currently assessing the impact of this guidance on its disclosures.Â Note 3 Accrued Liabilities Â The principal components of accrued liabilities consist of (in thousands):Â F-12 Â Â AnavexLife Sciences Corp.Notesto the Consolidated Financial StatementsSeptember30, 2024 â€“ Page 13Â Schedule of principal components of accrued liabilitiesÂ Â Â Â Â Â Â Â Â Â September 30, Â Â 2024Â 2023 Accrued investigator paymentsÂ $860Â Â $2,006Â Accrued compensation and benefitsÂ Â 1,527Â Â Â 1,360Â Fixed contract accrualsÂ Â â€”Â Â Â 38Â Milestone-based contract accrualsÂ Â 557Â Â Â 1,267Â All other accrued liabilitiesÂ Â 1,891Â Â Â 2,624Â Total accrued liabilitiesÂ $4,835Â Â $7,295Â Â Note 4 Other IncomeÂ Grant incomeÂ As of September 30, 2024,the Company had received a $1.0 million research grant awarded by the Michael J. Fox Foundation for Parkinsonâ€™s Research. The grantwill be used to fund a clinical trial of the Companyâ€™s lead compound, ANAVEXÂ®2-73 (blarcamesine) related to Parkinsonâ€™sdisease. Of the total, $0.5 million was received during the year ended September 30, 2023 and $0.5 million was received during the yearended September 30, 2021.Â The grant income has beendeferred when received and is being amortized to other income as the related research and development expenditures are incurred. Duringthe year ended September 30, 2024, the Company recognized $75,000 (2023: $25,000) of this grant on its statements of operations withingrant income. At September 30, 2024 an amount of $0.8 million (2023: $0.9 million) of this grant is recorded as deferred grant income,representing the amount of this grant which has not yet been amortized to other income. The Company will recognize this income on itsstatements of operations as the related expenditures are incurred to offset the income.Â Research and developmentincentive incomeÂ Research and developmentincentive income represents the income earned by Anavex Australia of the Australia R&D credit. This cash incentive is received byAnavex Australia, upon filing of a claim in connection with Anavex Australiaâ€™s annual income tax return.Â During the year ended September30, 2024, the Company recorded research and development incentive income of $2.3 million (AUD 3.5 million) (2023: $2.7 million (AUD 4.1million)) in respect of the Australia R&D credit for eligible research and development expenses incurred during the year. This amountis included within Other income (expense) on the consolidated statements of operations and comprehensive loss.Â At September 30, 2024, Incentiveand tax receivables includes $2.3 million (AUD 3.3 million) (2023: $2.5 million (AUD 3.9 million)) relating to Australia R&D creditsearned during the year that are expected to be reimbursed upon filing of the Companyâ€™s annual claim under this program.Â The Australia R&D creditprogram is a self-assess program whereby the Company must assess its eligibility each year to determine (i) if the entity is eligible(ii) if the specific R&D activities are eligible and (iii) if the individual R&D expenditures have nexus to such R&D activities.The Company evaluates its eligibility under the tax incentive program as of each balance sheet date based on the most current and relevantdata available. Anavex Australia is able to continue to claim the R&D tax incentive for as long as it remains eligible and continuesto incur eligible research and development expenditures.Â F-13 Â Â AnavexLife Sciences Corp.Notesto the Consolidated Financial StatementsSeptember30, 2024 â€“ Page 14Â Although the Company believesthat it has complied with all the relevant conditions of eligibility under the program for all periods claimed, the ATO has the rightto review the Companyâ€™s qualifying programs and related expenditures for a period of four years. If such a review were to occur,the ATO may have different interpretations of certain eligibility requirements. If the ATO disagreed with the Companyâ€™s assessmentsand any related subsequent appeals, it could require adjustment to and repayment of current or previous yearsâ€™ claims already received.Additionally, if the Company was unable to demonstrate a reasonably arguable position taken on such claims, the ATO could also assesspenalties and interest on any such adjustments.Â Currently, the Companyâ€™stax incentive claims from 2020 to 2024 are open to potential review by the ATO. Additionally, the period open for review is indefiniteif the ATO suspects fraud. The Company has not provided any allowance for any such potential adjustments, should they occur in the future.Â Note 5 Equity OfferingsÂ Common StockÂ Common shares are voting and are entitled to dividendsas declared at the discretion of the Board of Directors.Â Preferred StockÂ The Companyâ€™s Board of DirectorsÂ (the â€œBoardâ€)Â hasthe authority to issue preferred stock in one or more series and to fix the rights, preferences, privileges, restrictions and the numberof shares constituting any series or the designation of the series.Â 2023 Purchase AgreementÂ On February 3, 2023, the Company entered into a $150.0million purchase agreement (the â€œ2023 Purchase Agreementâ€) with Lincoln Park Capital Fund, LLC (â€œLincoln Parkâ€),pursuant to which the Company has the right to sell and issue to Lincoln Park, and Lincoln Park is obligated to purchase, up to $150.0million in value of its shares of common stock from time to time over a three-year period until February 3, 2026.Â In consideration for entering into the 2023 PurchaseAgreement, the Company issued to Lincoln Park 75,000 shares of common stock as a commitment fee (the â€œinitial commitment sharesâ€)and agreed to issue up to an additional 75,000 shares pro rata, when and if, Lincoln Park purchased, at the Companyâ€™s discretion,the $150.0 million aggregate commitment. The Company determined the fair value of the initial commitment shares was $0.8 million withreference to the closing price of the Companyâ€™s shares on the Purchase Agreement date. In addition, the Company incurred third partyexpenses of $0.1 million in connection with entering into the Purchase Agreement. These amounts were expensed to other financing expenseon the statements of operations during the year ended September 30, 2023.Â During the year ended September 30, 2024, the Companyissued to Lincoln Park an aggregate of 2,455,646 shares of common stock under the 2023 Purchase Agreement, including 2,450,000 sharesof common stock for an aggregate purchase price of $11,283,200 and 5,646 commitment shares. During the year ended September 30, 2023,the Company issued to Lincoln Park an aggregate of 3,288,943 shares of common stock under the 2023 Purchase Agreement, including 3,275,000shares of common stock for aggregate proceeds of $27.9 million

andÂ 13,943Â commitment shares.Â At September 30, 2024, an amount of $110.8 millionremained available under the 2023 Purchase Agreement.Â 2020 Sales AgreementÂ The Company entered into a Controlled Equity OfferingSales Agreement on July 6, 2018, which was amended and restated on May 1, 2020 (the â€œ2020 Sales Agreementâ€) with Cantor FitzgeraldÂ &Co. and SVB Leerink LLC (together the â€œSales Agentsâ€), pursuant to which the Company could offer and sell shares of commonstock registered under an effective registration statement from time to time through the Sales Agents (the â€œOfferingâ€).Â F-14 Â Â AnavexLife Sciences Corp.Notesto the Consolidated Financial StatementsSeptember30, 2024 â€“ Page 15Â During the years ended September 30, 2024 and 2023,no shares were sold pursuant to the Offering. At September 30, 2023, an amount of $142.4 million was registered pursuant to an effectiveregistration statement.Â On July 24, 2024, the Company terminated the 2020Sales Agreement.Â Note 6 Commitments and ContingenciesÂ LeaseÂ TheCompany leases office space under an operating lease with an initial term of 12 months or less. Under the terms of the office lease, theCompany is required to pay its proportionate share of operating costs. Â Theoperating lease costs were as follows (in thousands):Â Schedule of operating lease costsÂ Â Â Â Â Â Â Â Â Â Years ended September 30, Â Â 2024Â 2023 Operating lease costsÂ $125Â Â $118Â Â Employee 401(k) Benefit PlanÂ TheCompany has a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code. The plan covers all United States basedemployees. United States based employees eligible to participate in the plan may contribute up to the current statutory limits under theInternal Revenue Service regulations. The 401(k) plan permits the Company to make additional matching contributions on behalf of contributingemployees. Â TheCompany made matching contributions under the 401(k) plan as follows (in thousands):Â Schedule of contributions under the planÂ Â Â Â Â Â Â Â Â Â Years ended September 30, Â Â 2024Â 2023 Contributions to 401(k) planÂ $279Â Â $232Â Â LitigationÂ The Companyis subject to claims and legal proceedings that arise in the ordinary course of business. Such matters are inherently uncertain, and therecan be no guarantee that the outcome of any such matter will be decided favorably to the Company or that the resolution of any such matterwill not have a material adverse effect upon the Companyâ€™s consolidated financial statements. The Company does not believe thatany of such pending claims and legal proceedings will have a material adverse effect on its consolidated financial statements.Â On March 13,2024, a shareholder class action complaint was filed in the United States District Court for the Southern District of New York and itnamed the Company and an officer of the Company as Defendants. The complaint was amended on July 12, 2024. The complaint alleges violationsof the Securities and Exchange Act of 1934 associated with disclosures and statements made with respect to certain clinical trials forANAVEXÂ®2-73 related to Rett syndrome. The complaint seeks unspecified damages, as well as costs, including counsel andexpert witness fees, on behalf of a class of investors.Â The Company believes the lawsuit is without merit and the Company deniesany liability or wrongdoing and has filed motions to dismiss the complaints, which is awaiting a decision by the Court. No amount hasbeen recorded in these consolidated financial statements for any loss contingencies associated with this lawsuit as the Company believesthat it is not probable that any loss will occur.Â F-15 Â Â AnavexLife Sciences Corp.Notesto the Consolidated Financial StatementsSeptember30, 2024 â€“ Page 16Â On May 8, 2024,a similar complaint was filed in the same court by Kenneth Downing, a purported shareholder of the Company, against the same defendants.The Company believed that this lawsuit was also without merit and filed a motion to dismiss the complaint. Plaintiff Downing voluntarilydismissed this complaint subsequent to the filing of the motion to dismiss.Â On or aboutMay 13, 2024, a derivative lawsuit was filed against the Company (as nominal defendant), an officer of the Company, and members of theCompanyâ€™s Board of Directors in the U.S. District Court for the District of Nevada by another purported shareholder. The complaintasserts various common law claims (including breach of fiduciary duty) and violation of Section 14(a)of the Securities Exchange Act regardingthe same or similar allegations at issue in the purported class action lawsuit related to disclosures and statements made about certainclinical trials related to Rett Syndrome. The Company believes this lawsuit is without merit and the Company denies any liability or wrongdoing.The parties are currently due to file a proposed schedule for the anticipated motion to dismiss by the Company and the officer of theCompany (the other named defendants have not been served with the complaint) on or before January 15, 2025.Â No amount has been recordedin these consolidated financial statements for any loss contingencies associated with this lawsuit as the Company believes that it isnot probable that any loss will occur.Â We know of noother material pending legal or governmental proceedings, other than ordinary routine litigation incidental to our business, to whichour Company or our subsidiaries are a party or of which any of their property is subject. There are no other proceedings in which anyof our directors, officers or affiliates, or any registered or beneficial stockholder holding more than 5% of our shares, or any associateof such persons, is an adverse party or has a material interest adverse to our or our subsidiariesâ€™ interest.Â Share Purchase WarrantsÂ A summary of the status of the Companyâ€™s outstandingshare purchase warrants is presented below:Â Schedule of share purchase warrants outstandingÂ Â Â Â Â Â Â Â Â Â Â Number of WarrantsÂ Weighted Average Exercise Price ($) Balance, September 30, 2023Â Â Â 160,000Â Â Â 3.72Â ExpiredÂ Â Â (150,000)Â Â 3.17Â Balance, September 30, 2024Â Â Â 10,000Â Â Â 12.00Â Â At September 30, 2024, the Company had 10,000 sharepurchase warrants outstanding exercisable at $12.00 per share until April 21, 2026.Â Stockâ€“based CompensationPlanÂ 2015 Stock Option PlanÂ On September 18, 2015, the Companyâ€™s Board approveda 2015 Omnibus Incentive Plan (the â€œ2015 Planâ€), which provided for the grant of stock options and restricted stock awardsto directors, officers, employees and consultants of the Company.Â The maximum number of our common shares reserved forissue under the plan was 6,050,553 shares, subject to adjustment in the event of a change of the Companyâ€™s capitalization.Â 2019 Stock Option PlanÂ On January 15, 2019, the Board approved the 2019 OmnibusIncentive Plan (the â€œ2019 Planâ€), which provides for the grant of stock options and restricted stock awards to directors,officers, employees, consultants and advisors of the Company.Â F-16 Â Â AnavexLife Sciences Corp.Notesto the Consolidated Financial StatementsSeptember30, 2024 â€“ Page 17Â The maximum number of our common shares reserved forissue under the plan was 6,000,000 shares, subject to adjustment in the event of a change of the Companyâ€™s capitalization.Â During the year ended September 30, 2022, 406,453options previously available under the 2019 Plan and the 2015 Plan became available under the 2022 Plan (as defined below).Â 2022 Stock Option PlanÂ On March 25, 2022, the Board approved the 2022 OmnibusIncentive Plan (the â€œ2022 Planâ€). The 2022 Plan was approved by stockholders on May 24, 2022. Under the terms of the 2022Plan, 10,000,000 additional shares of Common Stock will be available for issuance under the plan, in addition to the shares availableunder the 2019 Plan and the 2015 Plan. Any awards outstanding under a previous stock option plan will remain subject to and be paid undersuch plan, and any shares subject to outstanding awards under a previous plan that subsequently cease to be subject to such awards (otherthan by reason of settlement of the awards in shares) will automatically become available for issuance under the 2022 Plan.Â The 2022 Plan provides that it may be administeredby the Board, or the Board may delegate such responsibility to a committee. The exercise price will be

determined by the Board at thetime 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, thenthe exercise price shall not be less than 110% of fair market value of the Companyâ€™s shares of common stock on the grant date. Stockoptions may be granted under the 2022 Plan for an exercise period of up to ten years from the date of grant of the option or such lesserperiods as may be determined by the Board, subject to earlier termination in accordance with the terms of the 2022 Plan. At September30, 2024, 5,267,500 options had been issued under the 2022 Plan and 5,462,202 options were available for issue under the 2022 Plan.Â The following summarizes information about stock optionactivity during the years ended September 30, 2024 and 2023:Â Schedule of stock option activityÂ Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Number of OptionsÂ Weighted Average Exercise Price ($)Â Weighted Average Grant Date Fair Value ($)Â Aggregate intrinsic value ($) Outstanding, October 1, 2022Â Â Â 13,169,616Â Â Â 6.61Â Â Â 4.96Â Â Â 62,267,309Â GrantedÂ Â Â 1,959,000Â Â Â 9.30Â Â Â 6.60Â Â Â â€”Â ExercisedÂ Â Â (759,753)Â Â 2.34Â Â Â 0.95Â Â Â 4,629,026Â ForfeitedÂ Â Â (257,083)Â Â 12.00Â Â Â 6.74Â Â Â â€”Â Outstanding, September 30, 2023Â Â Â 14,111,780Â Â Â 7.12Â Â Â 5.27Â Â Â 22,290,069Â GrantedÂ Â Â 1,860,500Â Â Â 5.47Â Â Â 3.95Â Â Â â€”Â ExercisedÂ Â Â (273,360)Â Â 2.53Â Â Â 1.11Â Â Â 601,407Â ForfeitedÂ Â Â (661,166)Â Â 11.67Â Â Â 5.00Â Â Â â€”Â Outstanding, September 30, 2024Â Â Â 15,037,754Â Â Â 6.80Â Â Â Â Â Â Â 15,825,791Â Exercisable, September 30, 2024Â Â Â 9,910,590Â Â Â 5.52Â Â Â Â Â Â Â 15,176,855Â Â The following summarizes information about stock optionsat September 30, 2024 by a range of exercise prices:Â F-17 Â Â AnavexLife Sciences Corp.Notesto the Consolidated Financial StatementsSeptember30, 2024 â€“ Page 18Â Schedule of summarizes information about stock optionsÂ Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â WeightedÂ Â Â Â Â Â Â Â Â averageÂ WeightedÂ Â Â Weighted Â Â Â Â Number ofÂ remainingÂ averageÂ Number ofÂ average Range of exercises pricesÂ outstandingÂ contractual lifeÂ exerciseÂ vestedÂ exercise FromÂ ToÂ optionsÂ (in years)Â priceÂ optionsÂ price $0.92Â Â $3.00Â Â Â 3,015,700Â Â Â 3.79Â Â $2.39Â Â Â 3,015,700Â Â $2.39Â $3.01Â Â $5.00Â Â Â 2,267,500Â Â Â 4.01Â Â $3.42Â Â Â 2,056,250Â Â $3.31Â $5.01Â Â $9.00Â Â Â 6,640,554Â Â Â 6.07Â Â $6.58Â Â Â 3,473,639Â Â $6.21Â $9.01Â Â $13.00Â Â Â 1,649,000Â Â Â 7.33Â Â $10.26Â Â Â 760,000Â Â $10.50Â $13.01Â Â $25.00Â Â Â 1,465,000Â Â Â 6.45Â Â $18.18Â Â Â 605,001Â Â $18.47Â Â Â Â Â Â Â Â Â Â 15,037,754Â Â Â 5.48Â Â $6.80Â Â Â 9,910,590Â Â $5.52Â Â Â The weighted average per share fair value of optionsvested at September 30, 2024 was $4.34 (2023: $3.94). At September 30, 2024, the weighted average contractual life of options outstandingwas 5.48 years (2023: 6.0 years) and for options exercisable was 4.03 years (2023: 4.75 years).Â The aggregate intrinsic value is calculated as thedifference between the exercise price of the underlying awards and the quoted market price of the Companyâ€™s stock for the optionsthat were in-the-money at September 30, 2024.Â The Company recognized share-based compensationexpense of $9.4 million during the year ended September 30, 2024 (2023: $16.4 million) in connection with the issuance and vesting ofstock options in exchange for services. These amounts have been included in general and administrative expenses and research and developmentexpenses on the Companyâ€™s consolidated statements of operations as follows (in thousands):Â Schedule of general and administrative expenses and research and development expensesÂ Â Â Â Â Â Â Â Â Â Years ended September 30, Â Â 2024Â 2023 General and administrativeÂ $3,625Â Â $5,558Â Research and developmentÂ Â 5,813Â Â Â 10,812Â Total share-based compensationÂ $9,438Â Â $16,370Â Â An amount of approximately $8.4 million in share-basedcompensation is expected to be recorded over the remaining term of such options and warrants through fiscal 2027.Â The fair value of each option andwarrant award is estimated on the date of grant using the Black Scholes option pricing model based on the following weighted average assumptions:Â Schedule of weighted average assumptions for fair value of each option awardÂ Â Â Â Â Â Â Â Â Â 2024Â 2023 Risk-free interest rateÂ Â 4.28%Â Â 3.70% Expected life of options (years)Â Â 5.78Â Â Â 5.64Â Annualized volatilityÂ Â 84.81%Â Â 85.13% Dividend rateÂ Â 0.00%Â Â 0.00% Â The fair value of stock compensation charges recognizedduring the years ended September 30, 2024 and 2023 was determined with reference to the quoted market price of the Companyâ€™s shareson the grant date.Â F-18 Â Â AnavexLife Sciences Corp.Notesto the Consolidated Financial StatementsSeptember30, 2024 â€“ Page 19Â Note 7 Income Taxes Â The Companyâ€™s U.S. and foreign loss before incometaxes are set forth below (in thousands):Â Schedule of loss before income taxesÂ Â Â Â Â Â Â Â Â Â 2024Â 2023 United StatesÂ $(39,195)Â $(41,198) ForeignÂ Â (3,807)Â Â (6,300) TotalÂ $(43,002)Â $(47,498) Â The components of net deferred income tax assets as of September 30, 2024and 2023 are as follows (in thousands):Â Schedule of components of net deferred income tax assetsÂ Â Â Â Â Â Â Â Â Â 2024Â 2023 Net operating loss carryforwardsÂ $48,134Â Â $46,462Â Research and development tax credit carryforwardsÂ Â 4,203Â Â Â 2,713Â Share-based compensationÂ Â 21,091Â Â Â 18,593Â Research and development capitalizationÂ Â 15,104Â Â Â 7,219Â Unpaid chargesÂ Â 3,197Â Â Â 1,559Â Intangible asset costsÂ Â 758Â Â Â 593Â Foreign exchange and otherÂ Â (254)Â Â 49Â Valuation allowance of deferred tax assetsÂ Â (92,233)Â Â (77,188) Net deferred tax assetsÂ $â€”Â Â $â€”Â Â A reconciliation of income tax expense at the statutoryfederal income tax rate and income taxes as reflected in the consolidated financial statements for the years ended September 30, 2024and 2023 is as follows (in thousands):Â Schedule of reconciliation of income tax expenseÂ Â Â Â Â Â Â Â Â Â 2024Â 2023 Income tax benefit at statutory federal rateÂ $(9,030)Â $(9,975) Foreign income taxed at other ratesÂ Â (61)Â Â â€”Â Permanent differences relating to share-based compensationÂ Â (10)Â Â (601) Permanent differences relating to GILTI inclusionÂ Â â€”Â Â Â 165Â Other permanent differencesÂ Â (276)Â Â 273Â Research and development credits, netÂ Â (860)Â Â (37) State and local taxesÂ Â (3,821)Â Â (4,122) Adjustment to true up to prior yearsâ€™ tax provisionÂ Â (1,128)Â Â 206Â Change in valuation allowancesÂ Â 15,186Â Â Â 14,098Â Income tax expenseÂ $â€”Â Â $7Â Â As of September 30, 2024, the Company had U.S. federalnet operating loss carryforwards of approximately $128.5 million (2023: $126.3 million) of which $37.7 million will begin to expire in2025 and $90.8 million can be carried forward indefinitely, state and local net operating loss carryforwards of approximately $ 16.9 million(2023: $16.6 million) which will begin to expire in 2036, and Research and Development tax credits of approximately $4.3 million (2023:$2.7 million) which will begin to expire in 2029. The calculation of the Research and Development tax credits, by their nature, involveestimates and subjectivity. If examined by the U.S. federal and state tax authorities, it is possible that some portion of these creditcarryforwards would be disputed by the tax authorities.Â The Company had approximately $16.6 million (approximatelyAU$23.9 million) (2023: $12.9 million (approximately AU$20.1 million)) of net operating loss carryforwards in Australia, which have anindefinite life, available to offset future taxable income in those jurisdictions.Â F-19 Â Â AnavexLife Sciences Corp.Notesto the Consolidated Financial StatementsSeptember30, 2024 â€“ Page 20Â The Company evaluates its valuation allowance requirementsbased on available evidence. When circumstances change, and this causes a change in managementâ€™s judgment about the recoverabilityof deferred tax assets, the impact of the change on the valuation allowance is reflected in current income. Because management of theCompany does not currently believe that it is more likely than

not that the Company will receive the benefit of these assets, a valuationallowance has been established at September 30, 2024 and 2023.Â The Tax Cuts and Jobs Act of 2017 (TCJA) has modifiedthe IRC 174 expenses related to research and development for tax years beginning after December 31, 2021. Under the TCJA, the Companymust now capitalize the expenditures related to research and development activities and amortize over five years for U.S. activities and15 years for non-U.S. activities using a mid-year convention. Therefore, the capitalization of research and development costs in accordancewith IRC 174 has resulted in a gross deferred tax assets at September 30, 2024 of $15.1 million (2023: $7.2 million).Â Uncertain Tax PositionsÂ The Company files income tax returns in the U.S. federaljurisdiction and various state and local and foreign jurisdictions. The Companyâ€™s tax returns are subject to tax examinations byU.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 2005.Â Under the provisions of the Internal Revenue Code,the net operating loss (â€œNOLâ€) carryforwards are subject to review and possible adjustment by the Internal Revenue Serviceand state tax authorities. Under Section 382 of the Internal Revenue Code, NOL and tax credit carryforwards may become subject to an annuallimitation in the event of an over 50% cumulative change in the ownership interest of significant stockholders over a three-year period,as well as similar state tax provisions.Â The Company conducted a Section 382 study during theyear ended September 30, 2021 and determined that, during the year ended September 30, 2015, there was a change in ownership which resultedin $25.8 million of federal NOLs being subject to an annual limitation. During the year ended September 30, 2021, the Company reducedits federal NOLs by $12.1 million and its Research and Development tax credit carryforwards by $0.8 million, which are the amount of taxassets that will expire unutilized pursuant to the Section 382 study. This resulted in a reduction of $2.5 million of NOLs and $0.8 millionof research and development credits and a corresponding reduction in the valuation allowance of $3.3 million, which was recorded in the2021 fiscal year. Subsequent ownership changes in future years could trigger additional limitations of the Companyâ€™s NOLs.During the year ended September 30, 2024 and 2023 the Company determined that there were no changes in ownership pursuant to Section 382.Â As of September 30, 2024, the Company did not provideany foreign withholding taxes related to its foreign subsidiariesâ€™ undistributed earnings, as such earnings have been retained andare intended to be indefinitely reinvested to fund ongoing operations of the foreign subsidiaries. It is not practicable to estimate theamount of taxes that would be payable upon remittance of these earnings, because such tax, if any, is dependent upon circumstances existingif and when remittance occur.Â Note8 Subsequent EventsÂ The Company evaluates subsequent events occurringbetween the most recent balance sheet date and the date the financial statements are available to be issued in order to determine whetherthe subsequent events are to be recorded and/or disclosed in the Companyâ€™s financial statements and footnotes. The financial statementsare considered to be available to be issued at the time they are filed with the Securities and Exchange Commission (SEC).Â There were no subsequent events or transactions thatrequired recognition or disclosure in the consolidated financial statements.Â F-20 Â Â ITEM 9. CHANGES IN AND DISAGREEMENTSWITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL MATTERSÂ Not ApplicableÂ ITEM 9A. CONTROLS AND PROCEDURESÂ Disclosure Controls and ProceduresÂ We maintain disclosure controls and procedures thatare designed to provide reasonable assurance that material information required to be disclosed in our periodic reports filed under theExchange Act is recorded, processed, summarized, and reported within the time periods specified in the SECâ€™s rules and forms andto provide reasonable assurance that such information is accumulated and communicated to our management, our chief executive officer andour principal financial officer, to allow timely decisions regarding required disclosure.Â We carried out an evaluation, under the supervisionand with the participation of our management, including our principal executive and principal financial officer, of the effectivenessof the design and operation of our disclosure controls and procedures, as defined inÂ RuleÂ 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 procedureswere effective as of September 30, 2024.Â Managementâ€™s Annual Report on InternalControl over Financial Reporting Â Our management is responsible for establishing andmaintaining adequate internal control over financial reporting as defined in RulesÂ 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 FinancialOfficer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria establishedin the framework inÂ Internal Control â€” Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of theTreadway Commission (â€œCOSOâ€).Â Because of its inherent limitations, internal controlover financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periodsare subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with thepolicies or procedures may deteriorate.Â Based on this evaluation, our management concludedthat our internal controls over financial reporting were effective as of September 30, 2024.Â Changes in Internal Control over Financial ReportingÂ During the quarter ended September 30, 2024, therewere no material changes in our internal control over financial reporting identified in managementâ€™s evaluation pursuant to Rules13a 15(d) or 15d 15(d) of the Exchange Act that materially affected, or are reasonably likely to materially affect, our internal controlsover financial reporting.Â ITEM 9B OTHER INFORMATIONÂ None of our directors or Section 16 officers adopted,modified or terminated a â€œRule 10b5-1 trading arrangementâ€ or â€œnon-Rule 10b5-1 trading arrangementâ€ (in each case,as defined in Item 408(a) of Regulation S-K) during the three-month period ended September 30, 2024.Â ITEM 9C DISCLOSURE REGARDINGFOREIGN JURISDICTIONS THAT PREVENT INSPECTIONSÂ Not applicable.Â 71 Â Â PART IIIÂ ITEM 10 DIRECTORS, EXECUTIVEOFFICERS AND CORPORATE GOVERNANCEÂ Directors and Executive OfficersÂ Our directors are to be elected at our annual meetingand each director elected is to hold office until his or her successor is elected and qualified. Our Board of Directors may remove ourofficers at any time.Â Our directors and executive officers, their ages,positions held, and duration of such, are as follows:Â Name Position Age Date first appointed Christopher Missling, PhD Director, President, Chief Executive Officer, Secretary 59 July 5, 2013 Jiong Ma, PhD Director, Chair 60 May 25, 2021 Athanasios Skarpelos Director 58 January 9, 2013 Claus van der Velden, PhD Director 52 March 2, 2018 Steffen Thomas, PhD Director 59 June 15, 2015 Peter Donhauser, D.O. Director 59 February 8, 2017 Sandra Boenisch, CPA, CGA Principal Financial Officer, Treasurer 43 October 1, 2015 Â Board Leadership StructureÂ The Board of Directors is composed of a majority ofindependent directors and the Chief Executive Officer of the Company.Â Our Board of Directors has appointed an independentBoard Chair, Dr. Jiong Ma. As Board Chair, Dr. Ma has the authority, among other things, to call and preside over meetings of our Board,to set meeting agendas, and to determine materials to be distributed to the Board. The Company believes separation of the positions ofBoard Chair and Chief Executive Officer reinforces the independence of our Board in its oversight of the business and affairs of the Company.In addition, the Company believes that having an independent

Board Chair creates an environment that is more conducive to objective evaluationand oversight of managementâ€™s performance, increasing management accountability and improving the ability of our Board to monitorwhether managementâ€™s actions are in the best interests of the Company and its stockholders.Â The Audit Committee, Compensation Committee, and Nominatingand Corporate Governance Committee each have oversight over specific areas of responsibility, as discussed further below.Â Board of Directorsâ€™ Role in Risk OversightÂ The Board of Directors is responsible for oversightof the Companyâ€™s risk management process. The Board administers this oversight function directly through the Board of Directorsas a whole, as well as through the committees of the Board. Areas of focus include economic risk, operational risk, financial risk (accounting,investment or liquidity, and tax), competitive risk, legal and regulatory risk, cybersecurity risk and compliance and reputational risks.The Board of Directors is supported by regular reporting by management, which is designed to give the Board of Directors visibility overthe Companyâ€™s operations and activities to adequately identify key risks and understand managementâ€™s risk mitigation strategies.Â Business ExperienceÂ The following is a brief account of the educationand business experience of directors and executive officers during at least the past five years, indicating their principal occupationsduring the period, and the names and principal businesses of the organizations by which they were employed.Â 72 Â Â Christopher Missling, PhD. Christopher Misslinghas over twenty years of healthcare industry experience in big pharmaceutical, biotech and investment banking. Most recently, from March2007 until his appointment by our Company, Dr. Missling served as the head of healthcare investment banking at Brimberg & Co. in NewYork, New York. In addition, 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 Managementand WHU Otto Beisheim School of Management.Â Jiong Ma, PhD.Â Jiong Ma has over 25 yearsof experience in investing, building, and scaling of companies with a focus on innovative product launches in digital health, technologyand the new energy transition. Dr. Ma is a General Partner of Phoenix Venture Partners. She serves as Lead Independent Board Directorof SES AI Corporation (NYSE: SES), Chairs the Compensation Committee, and as a member of Audit, Nominating, and Strategic Investment Committee.Dr. Ma served as senior partner and a member of the investment committee at Braemar Energy Ventures (â€œBraemarâ€). While atBraemar, Dr. Ma led investments in more than 15 companies involved in either resource efficiency, e-mobility, industrial digitalization,renewable energy, or deep tech, and has achieved multiple successful exits through M&A and IPO. Dr. Ma has significant knowledge andexpertise in the technology industry, including information security. Prior to Braemar Energy Ventures, she was with the Venture CapitalGroup at 3i Group, a global private equity firm, where she led investments across multiple stages in Digital Health, TMT and Cleantech.Preceding the Venture Capital Group at 3i, Dr. Ma held several senior positions at Lucent Technologies and Bell Labs. Her responsibilitiesincluded lead roles in product portfolio strategy, new product launches for Optical and Data Networking, and research and product development.Dr. Ma was also a founding team member of Onetta Inc., a fiber networks company. She has a PhD in Electrical and Computer Engineeringfrom the University Colorado Boulder and an MS in Electrical Engineering from Worcester Polytechnic Institute. Dr. Ma is a Kauffman Fellow.Â Claus van der Velden, PhD. Claus van der Velden,PhD brings significant expertise in management, accounting, internal controls, information security and risk management. Since May 2021,he has served as Managing Director (Chief Financial Officer) of NetCologne GmbH, a regional telecommunication provider in Germany. FromJuly 2011 to May 2021, he served as corporate head of Management Accounting, Internal Audit and Risk Management at Stroeer SE & CoKGaA, a publicly listed German digital media company. As the prior head of internal audit at Stroeer SE & Co KGaA, Dr. van der Veldenhas experience in the area of information security risk assessment, and the internal control tools, processes, and policies needed tocounter information security threats. Previously, Dr. van der Velden served as the Director of Corporate Business Controlling for theNutrition & Health business unit at Cognis, a worldwide supplier of global nutritional ingredients and specialty chemicals. In thisposition, 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 mostlynatural-source ingredients for the food and healthcare industries. Dr. van der Velden started his career as a strategy consultant at aninternational marketing and strategy consultancy firm. He studied in Kiel and Stockholm and received a degree in economics from the Universityof Kiel and later obtained his doctorate in business management from the WHU-Otto Beisheim School of Management where he also previouslytaught economics.Â Athanasios Skarpelos. Athanasios (Tom) Skarpelosis a self-employed investor with over 20 years of experience working with private and public companies with a focus on biotechnology companiesinvolved in drug discovery and drug development projects. His experience has led to relationships with researchers at academic institutesin Europe and North America. Mr. Skarpelos is a founder of Anavex.Â Steffen Thomas, PhD. Steffen Thomas has over15 years of experience as a European patent attorney and is currently practicing at Epping Hermann Fischer, a major intellectual propertylaw firm in Europe. Previously, he worked for Japan-based Takeda Pharmaceutical Company, the largest pharmaceutical company in Asia anda top firm worldwide, as an in-house patent attorney. Prior to that, he worked for Nycomed Pharma, acquired by Takeda in 2011 for approximatelyUSD $10 billion. Dr. Thomasâ€™ legal practice covers drafting of patent applications, prosecuting patent applications before nationaland international patent offices, defending and challenging patents in opposition, appeal, and nullity proceedings, enforcing patentsbefore the infringement courts, and preparing opinions on patentability and infringement in the technical field of chemistry. Dr. Thomashas particular expertise in small molecule pharmaceuticals. He holds MS and PhD degrees in Chemistry from the University of Munich.Â 73 Â Â Peter Donhauser, D.O. Peter Donhauser had morethan 20 years of expertise in clinical research prior to practicing osteopathic medicine with an integrated medical approach in privatepractice 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 ofOsteopathic Medicine (D.O.) from the German-American Academy for Osteopathy, or DAAO, a member of the European Register for OsteopathicPhysicians, or EROP, at the Philadelphia College of Osteopathic Medicine.Â Sandra Boenisch, CPA, CGA. Ms. Boenisch isa Chartered Professional Accountant (CPA, CGA) with approximately 20 years of accounting, audit and financial reporting experience ina variety of industries, both in the United States and Canada. Ms. Boenisch was an independent consultant, providing financial reportingservices to a range of public companies in the United States and Canada since January 2012. From 2008 until 2012, Ms. Boenisch was employedat BDO Canada LLP (Vancouver, BC) where she was hired as a Senior Accountant and was later promoted to Manager, Audit Assurance. Ms. Boenischspecialized in managing assurance engagements for public companies in the United States and Canada. Prior to that, Ms. Boenisch workedfor another public accounting

firm from 2001 to 2008. As an independent consultant, Ms. Boenisch has acquired considerable experiencein finance, governance, and regulatory compliance. She holds a BComm from Laurentian University.Â Family RelationshipsÂ There are no family relationships between any directoror executive officer.Â Involvement in Certain Legal ProceedingsÂ There are no material proceedings to which any directoror executive officer or any associate of any such director or officer is a party adverse to our Company or has a material interest adverseto our Company.Â Delinquent Section 16(a) Reports Â Section 16(a) of the ExchangeAct requires our officers and directors, and persons who beneficially own more than ten percent (10%) of our outstanding common stock,to file initial reports of ownership and reports of changes in ownership with the SEC. Such persons are required by SEC regulations tofurnish us with all copies of Section 16(a) forms they file.Â Based solely on our reviewof the forms furnished to us and written representations from certain reporting persons, we believe that all filing requirements applicableto our executive officers, directors and persons who own more than 10% of our common stock were complied with in fiscal year 2024, exceptfor the following late filings:Â Â·Form 4 filed January 12, 2024 for Sandra Boenisch;Â Â·Form 4 filed January 12, 2024 for ChristopherMissling;Â Â·Form 4 filed February 23, 2024 for Athanasios Skarpelos;Â Â·Form 4 filed February 23, 2024 for Jiong Ma;Â Â·Form 4 filed February 23, 2024 for Steffen Thomas;Â Â·Form 4 filed February 23, 2024 for Peter Donhauser; and Â Â·Form 4 filed February 23, 2024 for Claus van der Velden.Â 74 Â Â Business Code of Conduct & EthicsÂ Our Board adopted a code of business ethics and conduct(the â€œCode of Ethicsâ€), applicable to all of our executives, directors and employees. The Code of Ethics is availablein print to any stockholder that requests a copy. Copies may be obtained by contacting Investor Relations at our corporate headquarters.Our Code of Ethics is also available on our website at www.anavex.com/corporate-governance. We intend to make any disclosuresregarding amendments to, or waivers from, the Code of Business Conduct required under Form 8-K by posting such information on our website.Â Insider Trading PolicyÂ We have an Insider Trading Policy that provides guidelineswith respect to transactions in our securities by insiders and the handling of our confidential information and the confidential informationof the companies with which we engage in transactions or do business. The policy promotes compliance with U.S. federal, securities lawsthat prohibit certain persons who are aware of material non-public information relating to us from (1) purchasing, selling, or otherwiseengaging in transactions in our securities, or (2) providing material non-public information to other persons who may trade on the basisof that information. In addition, our Insider Trading Policy prohibits our directors, officers, employees and consultants from engagingin short sales, transactions in publicly traded options such as put, calls or other derivative securities, hedging transactions and otherinherently speculative transactions with respect to our stock at any time. Our policy further prohibits such persons from engaging intransactions involving any loan, pledge or other transfer of beneficial ownership of the Companyâ€™s securities without obtainingadvance clearance of the proposed transaction from our Insider Trading Compliance Officer.Â Information Regarding Committees of the Boardof DirectorsÂ The Board has an Audit Committee, a Compensation Committeeand a Nominating and Corporate Governance Committee. The following table provides membership and meeting information for 2024:Â Â Â NameÂ Â Audit CommitteeÂ Â Compensation CommitteeNominating and Corporate Governance CommitteeChristopher Missling, PhDÂ Â Â Jiong Ma, PhDXÂ Â Claus van der Velden, PhDX*X*X*Athanasios SkarpelosÂ Â Â Steffen Thomas, PhDXXXPeter Donhauser, D.O.Â XXMeetings in 2024421Â *Committee ChairÂ Audit Committee and Audit Committee FinancialExperts Â The Audit Committee is composed of four directors,each of whom is independent. The Audit Committee operates under a charter that was adopted by our Board of Directors. The Audit Committeeoversees and reports to our Board of Directors on various auditing and accounting-related matters, including, among other things, themaintenance of the integrity of our financial statements, reporting process and internal controls; the selection, evaluation, compensationand retention of our independent registered public accounting firm; legal and regulatory compliance, including our disclosure controlsand procedures; and oversight over our risk management policies and procedures.Â 75 Â Â Our Board of Directors has determined that Claus vander Velden is an â€œaudit committee financial expertâ€ as defined by applicable SEC and NASDAQ rules.Â The Audit Committee has reviewed and discussed theaudited consolidated financial statements with management. The Audit Committee has discussed with the Companyâ€™s independent registeredpublic accounting firm the matters required to be discussed by the applicable requirements of the Public Company Accounting OversightBoard (â€œPCAOBâ€) and the Securities and Exchange Commission (the â€œSECâ€). In addition, the Audit Committee has receivedthe written disclosures and the letter from the independent registered public accounting firm required by applicable requirements of thePCAOB regarding the firmâ€™s communications with the Audit Committee concerning independence and has discussed with the independentregistered accounting firm its independence from the Company and management. Based on the reviews and discussions referred to above, theAudit Committee recommended to the Board that the audited consolidated financial statements for the Company for the fiscal year endedSeptember 30, 2024 be included in this Annual Report on Form 10-K for the year ended September 30, 2024.Â The foregoing report has been furnished by the AuditCommittee.Â Claus van der Velden (Chairman)Â Jiong MaSteffen ThomasÂ Compensation CommitteeÂ The Compensation Committee is composed of three directors,each of whom is independent. The Compensation Committee operates under a charter that was adopted by our Board of Directors. The CompensationCommittee assists our Board of Directors in discharging its responsibilities relating to the compensation of our directors and executiveofficers. Its responsibilities include, among other things: reviewing, approving and recommending compensation programs and arrangementsapplicable to our officers; determining the objectives of our executive officer compensation programs; overseeing the evaluation of oursenior executives; administering our incentive compensation plans and equity-based plans, including reviewing and granting equity awardsto our executive officers; and reviewing and approving director compensation and benefits. The Compensation Committee can delegate toother members of our Board of Directors, or an officer or officers of the Company, the authority to review and grant share-based compensationfor employees who are not executive officers.Â The Compensation Committee has the responsibilitiesand authority designated by NASDAQ rules and the Compensation Committee Charter. Specifically, the Compensation Committee has the solediscretion to select and receive advice from a compensation consultant, legal counsel or other adviser and is directly responsible foroversight of their work. The Compensation Committee must also determine reasonable compensation to be paid to such advisors by us.Â The Compensation Committee met two times during fiscal2024 and acted by written consent as required.Â Nominating and Corporate Governance CommitteeÂ The Nominating and Corporate Governance Committee(the â€œNCG Committeeâ€) is appointed by the Board to oversee and evaluate the Boardâ€™s performance and the Companyâ€™scompliance 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 NCG Committee seeks to assemble a Board that possesses the appropriate balance of professional and

industry knowledge, financial expertiseand management experience that is necessary to oversee the Companyâ€™s business. The NCG also recognizes the importance of diversityin board composition, including diversity of experience, gender and ethnicity and seeks to continually strive towards optimal diversity.The NCG Committee operates under a charter that was adopted by our Board of Directors.Â 76 Â Â The NCG Committee met one time during fiscal 2024and also acted by written consent as required.Â ITEM 11. EXECUTIVE COMPENSATIONÂ Our Executive Compensation Program and PhilosophyÂ The intent of the Companyâ€™s compensation programfor our named executive officers is to attract and retain talent, to create incentives for and to reward excellent performance. We seekto compensate our named executive officers in a manner that is competitive, rewards performance that creates stockholder value, recognizesindividual contributions, and encourages long-term value creation.Â The Compensation Committee meets at least once peryear to review and evaluate the compensation of our named executive officers and each officerâ€™s performance. The Compensation Committeeutilizes quantitative and qualitative factors, including the accomplishment of initiatives, attitude, and leadership and applies overalljudgment to assess performance, taking into account the financial condition of the Company. In setting compensation, the CompensationCommittee considers the outcome of the most recent say-on-pay vote, as well as stockholder feedback throughout the year, when making compensationdecisions for our executive officers. In our most recent say-on-pay vote, conducted at our 2024 annual meeting of stockholders, held onJune 18, 2024, our stockholders approved the compensation of our named executive officers on an advisory basis, with 83.8% of the votescast in favor of the compensation of our named executive officers. Ultimately, the Compensation Committee seeks to evaluate, based onthe achievement of financial and nonfinancial objectives, the variable compensation, including special awards, of our named executiveofficers and decide on the base salary and target discretionary bonus for such persons taking into account relevant benchmark data.Â The Compensation Committee believes that a significantportion of each named executive officerâ€™s compensation opportunity should be tied to variable compensation and value creation forstockholders. The Compensation Committee believes this mix provides an appropriate balance between the financial security required toattract and retain qualified individuals, and the Compensation Committeeâ€™s goal of ensuring that the compensation of our named executiveofficers rewards performance that benefits stockholders over the long term.Â Compensation ConsultantsÂ The Compensation Committee makes recommendations tothe Board regarding the compensation of our named executive officers, 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 conditionsof their engagement. During fiscal 2024, the Compensation Committee did not engage any compensation consultants.Â Annual Discretionary Cash BonusesÂ The Company has an annual discretionary cash bonusprogram. We provide such bonuses to motivate executive officers to perform on behalf of general corporate goals and to perform in theirareas of responsibility. The Compensation Committee works with the Chief Executive Officer to evaluate the Companyâ€™s financial performanceof the prior year, and overall financial condition of the Company to determine if discretionary bonuses are to be paid. In addition, onan annual basis, our Compensation Committee independently evaluates the performance of our Chief Executive Officer in the prior year,as well as the overall financial condition of the Company to determine if a discretionary bonus of up to 20% of base salary shall be paidto the Chief Executive Officer.Â 77 Â Â Clawback PolicyÂ In November 2023, the Board adopted an executive officercompensation clawback policy that may be applied in the event of a material financial restatement. The clawback policy covers all of thenamed executive officers and includes all incentive-based compensation. Specifically, in the event of an accounting restatement, the Companymust recover, reasonably promptly, erroneously awarded compensation in amounts determined pursuant to the policy. Compensation that maybe recoverable under the policy includes cash or equity-based compensation for which the grant, payment or vesting (or any portion thereof)is or was predicated upon the achievement of specified financial results that are impacted by the material financial restatement, andthe amount of compensation that may be impacted by the clawback policy is the difference between the amount paid or granted, and the amountthat should have been paid or granted, if calculated on the updated financials. Recovery under the policy with respect to an executiveofficer will not require the finding of any misconduct by such executive officer or such executive officer being found responsible forthe accounting error leading to an accounting restatement. Our equity awards provide that the Company may annul an award if the granteeincurs a separation from service for â€œcauseâ€ (as defined in the agreements). In such case, all awards and any amounts or benefitsreceived or outstanding shall be subject to cancellation, recoupment, rescission, payback and other action in accordance with the termsof the clawback policy or any applicable law. In addition, in the event of a restatement of the Companyâ€™s financial statements dueto material noncompliance with any financial reporting requirement under the law, whether such noncompliance is the result of misconductor other circumstances, an employee shall be required to reimburse the Company for any amounts earned or payable with respect to an awardgranted under the Companyâ€™s equity plan to the extent required by law and the Companyâ€™s clawback policy.Â Stock Ownership GuidelinesÂ We do not have any stock ownership guidelines, ownershipgoals or holding requirements. If and as we succeed in achieving approval for and commercializing our product candidates, we expect thatwe will adapt the elements of our compensation program as appropriate and may include or substitute other elements in our compensationprogram. Changes in the elements of our compensation program may also reflect changes in the importance of tax or accounting treatmentsof a particular element of our compensation program.Â Policies and Practices for Granting Certain EquityAwardsÂ Our policies and practices regarding the grantingof equity awards are carefully designed to ensure compliance with applicable securities laws and to maintain the integrity of our executivecompensation program. The Compensation Committee is responsible for the timing and terms of equity awards to executives and other eligibleemployees.Â The timing of equity award grants is determined withconsideration to a variety of factors, including but not limited to, the achievement of pre-established performance targets, market conditionsand internal milestones. The Company does not follow a predetermined schedule for the granting of equity awardsÍ¾ instead, each grantis considered on a case-by-case basis to align with the Companyâ€™s strategic objectives and to ensure the competitiveness of ourcompensation packages.Â In determining the timing and terms of an equity award,the Board or the Compensation Committee may consider material nonpublic information to ensure that such grants are made in compliancewith applicable laws and regulations. The Boardâ€™s or the Compensation Committeeâ€™s procedures to prevent the improper use ofmaterial nonpublic information in connection with the granting of equity awards include oversight by legal counsel and, where appropriate,delaying the grant of equity awards until the public disclosure of such material nonpublic information.Â The Company is committed to maintaining transparencyin its executive compensation practices and to making equity awards in a manner that is not influenced by the timing of the disclosureof material nonpublic information for the purpose of affecting the value of executive compensation. The Company regularly reviews itspolicies and practices related to equity awards to ensure they meet

the evolving standards of corporate governance and continue to servethe best interests of the Company and its shareholders.Â 78 Â Â Summary Compensation Â The particulars of compensation paid to our namedexecutive officers for the last three completed fiscal years:Â Â Â Â Â Â Â Â Â Â All otherÂ Â Â Â Â Â Â Â Â OptionÂ Compen-Â Â Name and PrincipalÂ Â Â SalaryÂ BonusÂ AwardsÂ sationÂ Total PositionÂ YearÂ ($)Â ($)Â ($)Â ($)(1)Â ($) Christopher Missling, PhDÂ Â 2024Â Â Â 700,000Â Â Â 140,000Â Â Â 1,927,600Â Â Â 16,100Â Â Â 2,783,700Â President, Chief Executive Officer, and DirectorÂ Â 2023Â Â Â 700,000Â Â Â 124,753Â Â Â 3,066,200Â Â Â 3,500Â Â Â 3,894,453Â Â Â Â 2022Â Â Â 586,400Â Â Â 110,000Â Â Â 6,045,043Â Â Â 12,200Â Â Â 6,753,643Â Sandra Boenisch(2)Â Â 2024Â Â Â 201,468Â Â Â â€”Â Â Â 192,700Â Â Â 8,059Â Â Â 402,227Â Principal Financial Officer andÂ Â 2023Â Â Â 186,883Â Â Â â€”Â Â Â 306,700Â Â Â 7,475Â Â Â 501,058Â TreasurerÂ Â 2022Â Â Â 174,900Â Â Â â€”Â Â Â 277,603Â Â Â â€”Â Â Â 452,503Â Â (1)Comprised of employer matching of defined contribution savings plans.Â (2)Compensation to Ms. Boenisch denominated in Canadian Dollars and has been translated to US dollars at an exchange rate of 0.73733during the year ended September 30, 2024 (2023: 0.7416; 2022: 0.7831).Â Employment AgreementsÂ Christopher MisslingÂ We and Dr. Missling entered into an employment agreementdated July 5, 2013, as amended and extended most recently by the third amendment effective April 7, 2022 (the â€œCEO Employment Agreementâ€),whereby we currently pay Dr. Missling an annual base salary of $700,000. In addition, Dr. Missling is eligible to earn an annual cashbonus 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.Â Sandra BoenischÂ We and Ms. Boenisch entered into an amended and restatedemployment agreement dated October 4, 2017, as amended and extended, whereby we currently pay Ms. Boenisch an annual base salary of $279,840Canadian dollars. Ms. Boenisch is eligible for discretionary salary increases.Â Outstanding Equity Awards at Fiscal Year-EndÂ The following table sets forth for each named executiveofficer and director certain information concerning the outstanding equity awards as of September 30, 2024.Â 79 Â Â Option Awards Â Â Â Â Â Â EquityÂ Â Â Â Â Â Â Â Â IncentiveÂ Â Â Â Â Â Â Â Â Plan Awards:Â Â Â Â Â Â Â Â Â Number ofÂ Â Â Â Â Â Number ofÂ Number ofÂ SecuritiesÂ Â Â Â Â SecuritiesÂ SecuritiesÂ UnderlyingÂ Â Â Â Â Â UnderlyingÂ UnderlyingÂ UnexercisedÂ OptionÂ Â Â Â ExercisableÂ UnexercisableÂ UnearnedÂ ExerciseÂ Option Â Â OptionsÂ OptionsÂ OptionsÂ PriceÂ Expiration NameÂ (#)Â (#)Â (#)Â ($)Â Date ChristopherÂ Â 500,000Â Â Â â€”Â Â Â â€”Â Â Â 0.92Â Â Â April 2, 2025Â MisslingÂ Â 187,500Â Â Â â€”Â Â Â â€”Â Â Â 5.04Â Â Â Sept 18, 2025Â Â Â Â 379,625Â Â Â â€”Â Â Â â€”Â Â Â 6.26Â Â Â July 5, 2026Â Â Â Â 861,429Â Â Â â€”Â Â Â â€”Â Â Â 7.06Â Â Â July 18, 2026Â Â Â Â 500,000Â Â Â â€”Â Â Â â€”Â Â Â 3.28Â Â Â Sept 22, 2026Â Â Â Â 450,000Â Â Â â€”Â Â Â â€”Â Â Â 5.92Â Â Â May 12, 2027Â Â Â Â 400,000Â Â Â â€”Â Â Â â€”Â Â Â 3.30Â Â Â Dec 13, 2027Â Â Â Â 450,000Â Â Â â€”Â Â Â â€”Â Â Â 2.30Â Â Â May 15, 2028Â Â Â Â 409,500Â Â Â â€”Â Â Â â€”Â Â Â 2.58Â Â Â Oct. 1, 2028Â Â Â Â 750,000Â Â Â â€”Â Â Â â€”Â Â Â 3.15Â Â Â May 3, 2029Â Â Â Â 550,000Â Â Â â€”Â Â Â â€”Â Â Â 2.96Â Â Â January 6, 2030Â Â Â 550,000Â Â Â â€”Â Â Â â€”Â Â Â 5.49Â Â Â December 30, 2030Â Â Â Â â€”Â Â Â 500,000Â Â Â â€”Â Â Â 18.11Â Â Â August 2, 2031Â Â Â Â â€”Â Â Â 500,000Â Â Â â€”Â Â Â 7.54Â Â Â June 14, 2032Â Â Â 125,000Â Â Â 375,000Â Â Â â€”Â Â Â 10.09Â Â Â June 27, 2032Â Â Â Â â€”Â Â Â 500,000Â Â Â â€”Â Â Â 8.57Â Â Â March 31, 2033Â Â Â Â Â Â Â 500,000Â Â Â â€”Â Â Â 5.36Â Â Â February 20, 2034Â Sandra BoenischÂ Â 30,000Â Â Â â€”Â Â Â â€”Â Â Â 3.30Â Â Â Dec 13, 2027Â Â Â Â 30,000Â Â Â â€”Â Â Â â€”Â Â Â 2.30Â Â Â May 15, 2028Â Â Â Â 27,300Â Â Â â€”Â Â Â â€”Â Â Â 2.58Â Â Â Oct. 1, 2028Â Â Â Â 35,000Â Â Â â€”Â Â Â â€”Â Â Â 2.93Â Â Â June 4, 2029Â Â Â Â 70,000Â Â Â â€”Â Â Â â€”Â Â Â 2.96Â Â Â January 6, 2030Â Â Â Â 50,000Â Â Â â€”Â Â Â â€”Â Â Â 5.49Â Â Â December 30, 2030Â Â Â Â â€”Â Â Â 40,000Â Â Â â€”Â Â Â 18.11Â Â Â August 2, 2031Â Â Â Â 10,000Â Â Â 30,000Â Â Â â€”Â Â Â 10.09Â Â Â June 27, 2032Â Â Â Â â€”Â Â Â 50,000Â Â Â â€”Â Â Â 8.57Â Â Â March 31, 2033Â Â Â Â â€”Â Â Â 50,000Â Â Â â€”Â Â Â 5.36Â Â Â February 20, 2034Â Â Â On February 20, 2024, our Compensation Committee grantedoptions to our Chief Executive Officer and Principal Financial Officer, which vest in four equal tranches based on four performance milestonesincluding accomplishing (i) Regulatory submission of AD-004 for Alzheimerâ€™s disease (US or EU), (ii) Publication of a Fragile Xpreclinical study (iii) Initiation of new clinical study not yet announced and (iv) Readout of ANAVEX3-71 Phase 2 clinical trial in Schizophrenia.Â Compensation of Directors Â The table below shows the compensation of our directorswho were not our named executive officers for the fiscal year ended September 30, 2024:Â 80 Â Â NameÂ Fees Earned or Paid in Cash($)Â StockÂ Awards($)Â Â Â OptionÂ Awards($) (1)Â Non-Equity Incentive Plan Compensation($)Â Nonqualified Deferred Compensation Earnings ($)Â All Other Compensation($)Â Total($) Jiong MaÂ Â 41,000Â Â Â â€”Â Â Â 202,200Â Â Â â€”Â Â Â â€”Â Â Â 243,200Â Claus van der VeldenÂ Â 41,000Â Â Â â€”Â Â Â 202,200Â Â Â â€”Â Â Â â€”Â Â Â 243,200Â Athanasios SkarpelosÂ Â 25,000Â Â Â â€”Â Â Â 202,200Â Â Â â€”Â Â Â â€”Â Â Â 227,200Â Steffen ThomasÂ Â 25,000Â Â Â â€”Â Â Â 202,200Â Â Â â€”Â Â Â â€”Â Â Â 227,200Â Peter DonhauserÂ Â 25,000Â Â Â â€”Â Â Â 202,200Â Â Â â€”Â Â Â â€”Â Â Â 227,200Â Â (1) Includes stock option awards valued based on theaggregate grant date fair value of the award computed in accordance with FASB ASC Topic 718. The amounts shown in the table above do notnecessarily reflect the actual value that may be realized by theÂ non-employeeÂ director upon vesting. On September 30, 2024,the aggregate number of outstanding vested and unvested stock option awards held by each director was as follows: Dr. Ma possessed optionsto purchase 210,000 shares, Dr. van der Velden possessed options to purchase 355,500 shares, Mr. Skarpelos possessed options to purchase405,500 shares, Dr. Thomas possessed options to purchase 455,500 shares and Dr. Donhauser possessed options to purchase 355,500 shares.Â We currently compensate non-employee directors $25,000per year, paid quarterly. We compensate Dr. Ma an additional $4,000 per quarter for acting as Chair. We compensate Claus van der Veldenan additional $4,000 per quarter for performing the functions of Chairman of the Audit Committee, Compensation Committee and Nominatingand Corporate Governance Committee.Â We regularly grant members of the Board of Directorsawards of options. Each Board member is granted options initially when they join the Board of Directors, which typically vest over a three-yearperiod. Additionally, we grant awards on an annual basis. Annual awards of options typically vest in full on the first anniversary ofgrant date. In 2024, the annual grant was 50,000 options to each director.Â In addition, directors are entitled to reimbursementfor reasonable travel and other out-of-pocket expenses incurred in connection with attendance at meetings of our Board of Directors. OurBoard of Directors may award further special remuneration to any director undertaking any special services on our behalf other than servicesordinarily required of a director.Â Retirement or Similar Benefit PlansÂ There are no arrangements or plans in which we provideretirement or similar benefits for our directors or executive officers.Â Resignation, Retirement, Other Termination,or Change in Control ArrangementsÂ Potential Payments Upon TerminationÂ The Company is a party to employment contracts withour Chief Executive Officer and Principal Financial

Officer that contain provisions for payment of severance upon termination by eitherthe Company without cause or by the employee for good reason. General terms of these arrangements are described below.Â 81 Â Â Our CEO Employment Agreement with Dr. Missling containsprovisions regarding our obligations upon his termination and upon a Change in Control. Any capitalized term not defined herein is usedas defined in the CEO Employment Agreement. If Dr. Misslingâ€™s employment is terminated by us without Cause, he is entitled to receivepayments by us consisting of (i) reimbursement of any unpaid business expenses to which he is entitled to reimbursement that were incurredprior to the effective date of his termination, (ii) all vested compensation and benefits to which he is entitled as of the TerminationDate, (iii) a severance payment consisting of the three times the sum of (a) his annual salary in effect at the time of termination and(b) the average of the annual Bonuses payable to him for the last three completed calendar years prior to the Termination Date, (iv) alloutstanding and unvested stock options and all options previously vested will become and remain exercisable for no less than three yearsfrom the Termination Date; (v) all of his unvested and outstanding restricted stock, restricted stock units or other equity awards thatare unvested and outstanding as of the Termination Date shall vest and be settled within ten business days after the Termination Date,(vi) life insurance coverage until the end of the term of the CEO Employment Agreement; and (vii) continued participation in all medical,dental and hospitalization benefits plans or programs for Dr. Missling and his eligible dependents for 36 months or until he receivessimilar benefits at a new employer, at his sole cost. If Dr. Misslingâ€™s employment is terminated by him for Good Reason, he is entitledto receive the same as the above, however the severance payment will consist of three times his annual salary in effect at the time oftermination and two times the average annual Bonuses payable to him for the last three completed calendar years prior to the TerminationDate.Â If Dr. Missling was terminated by the Company withoutcause on September 30, 2024, he would have been entitled to a severance payment of $2.5 million. If Dr. Missling terminated his employmentfor Good Reason on September 30, 2024, he would have been entitled to a severance payment of $2.3 million.Â Our CFO Employment Agreement with Ms. Boenisch containsprovisions regarding our obligations upon her termination. Any capitalized term not defined herein is used as defined in the CFO EmploymentAgreement. Under the CFO Employment Agreement, if Ms. Boenisch is terminated without Cause, the Company shall pay Ms. Boenisch severancecompensation equal to six months base salary payable by the Company for the six-month period following the Termination. In addition, theCompany must provide Ms. Boenisch thirty (30) day notice of her Termination. If the Company opts to have Ms. Boenisch cease providingservices to the Company prior to the expiration of the thirty (30) day notice-period (the â€œNotice Periodâ€), Ms. Boenisch shallreceive the Compensation and Benefits for the full length of the Notice Period as if such period was not waived. In addition, any unvestedstock options or stock awards vesting in the contract year of Termination held by Ms. Boenisch as of the Date of Termination shall immediatelyvest.Â If Ms. Boenisch was terminated by the Company withoutcause on September 30, 2024, she would have been entitled to continued salary payments equal to $0.1 million in total.Â The following table presents accelerated vesting forcertain equity awards outstanding at the time of the executiveâ€™s termination for each Named Executive Officer, if employment wereterminated by either the Company without cause or by Dr. Missling for good reason on September 30, 2024:Â Â Â Vesting Upon Termination Named Executive OfficerÂ Unvested Stock Options (#)Â Stock Option Awards Â Estimated Benefit ($)(1) Dr. Christopher MisslingÂ Â 2,375,000Â Â Â 160,000Â Sandra BoenischÂ Â â€”(2)Â Â â€”Â Â (1) Estimated benefit based on the closing stock priceof $5.68 at September 30, 2024.Â (2) Ms. Boenischâ€™s unvested stock options atSeptember 30, 2024 all contained performance based vesting conditions, therefore such options would not automatically vest upon Termination.Â Potential Payments Upon Change in ControlÂ If the Company is subject to a Change in Control,then the CEO Employment Agreement and the CFO Employment Agreement provide that all previously granted but unvested stock options heldby Dr. Missling and Ms. Boenisch shall vest.Â 82 Â Â The following table presents accelerated vesting forcertain equity awards outstanding to the Named Executive Officer, if a change in control had occurred at September 30, 2024:Â Â Â Vesting Due to Change in Control Named Executive OfficerÂ Unvested Stock Options (#)Â Stock Option Awards Â Estimated Benefit ($)(1) Dr. Christopher MisslingÂ Â 2,375,000Â Â Â 160,000Â Sandra BoenischÂ Â 170,000Â Â Â 16,000Â Â (1) Estimated benefit based on the closing stock priceof $5.68 at September 30, 2024.Â For a complete description of these terms and conditions please referto the CEO Employment Agreement and CFO Employment Agreement (and their amendments) filed as exhibits to this Annual Report on Form 10-K.Â ITEM 12. SECURITY OWNERSHIPOF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.Â The following table sets forth, as of December 23,2024, certain information with respect to the beneficial ownership of our common stock by each stockholder known by us to be the beneficialowner of more than 5% of our common stock and by each of our current directors and our named executive officers and by our current directorsand executive officers as a group. We have determined the number and percentage of shares beneficially owned by such person in accordancewith Rule 13d-3 under the Securities Exchange Act of 1934. This information does not necessarily indicate beneficial ownership for anyother purpose.Â Title of classÂ Name and address of beneficial ownerÂ Amount and nature of beneficial ownershipÂ Percent of class (1) Directors and Named Executive Officers Common StockÂ Christopher Missling (CEO/Director)Â Â 7,363,264(2)Â Â 8.1% Common StockÂ Jiong Ma (Director, Chair)Â Â 110,000(3)Â Â *Â Common StockÂ Claus van der Velden (Director)Â Â 255,500(4)Â Â *Â Common StockÂ Athanasios Skarpelos (Director)Â Â 1,611,958(5)Â Â 1.9% Common StockÂ Steffen Thomas (Director)Â Â 360,500(6)Â Â *Â Common StockÂ Peter Donhauser (Director)Â Â 260,500(7)Â Â *Â Common StockÂ Sandra Boenisch (Principal Financial Officer)Â Â 275,262(8)Â Â *Â Common StockÂ Directors & Executive Officers as a group (7 persons)Â Â 10,236,984Â Â Â 11.1% 5% HoldersÂ Â Â Â Â Â Â Â Â Â Common StockÂ The Vanguard Group Â 100 Vanguard Blvd Â Malvern, PA 19355Â Â 4,360,648(9)Â Â 5.1% Common StockÂ BlackRock, Inc. Â 55 East 52nd Street Â New York, NY 10055Â Â 6,671,075(10)Â Â 7.9%Â *Less than 1%Â 83 Â Â (1)Percentage of ownership is based on 84,815,517 of our common stock issued and outstanding as of December23, 2024. Except as otherwise indicated, we believe that the beneficial owners of the common stock listed above, based on informationfurnished by such owners, have sole investment and voting power with respect to such shares, subject to community property laws whereapplicable. Beneficial ownership is determined in accordance with the rules of the Commission and generally includes voting or investmentpower with respect to securities. Shares of common stock subject to options or warrants currently exercisable or exercisable within 60days, are deemed outstanding for purposes of computing the percentage ownership of the person holding such option or warrants but arenot deemed outstanding for purposes of computing the percentage ownership of any other person.Â (2)Includes options to purchase 500,000 shares of our common stock at $0.92 per share, options to purchase187,500 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, optionsto 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 pershare,

options to purchase 450,000 shares of our common stock at $5.92 per share, options to purchase 400,000 shares of our common stockat $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 ourcommon stock at $2.58 per share, options to purchase 750,000 shares of our common stock at $3.15 per share, options to purchase 550,000shares of our common stock at $2.96 per share, options to purchase 550,000 shares of our common stock at $5.49 per share and options topurchase 125,000 shares of our common stock at $10.09 per share that are vested or are vesting within 60 days. Excludes options to purchase500,000 shares of our common stock at $18.11 per share, options to purchase 500,000 shares of our common stock at $7.54 per share, optionsto purchase 375,000 shares of our common stock at $10.09 per share, options to purchase 500,000 shares at $8.57 per share and optionsto purchase 500,000 shares of common stock at $5.36 per share that do not vest within 60 days.Â (3)Includes options to purchase 35,000 shares of our common stock at $13.01 per share, options to purchase25,000 shares of our common stock at $18.11 per share, options to purchase 33,333 shares of our common stock at $10.09 per share and optionsto purchase 16,667 shares of our common stock at $8.57 per share that have vested or are vesting within 60 days. Excludes options to purchase16,667 shares of our common stock at $10.09 per share, options to purchase 50,000 shares of our common stock at $8.57 per share and optionsto purchase 50,000 shares of common stock at $5.36 per share that do not vest within 60 days.Â (4)Includes options to purchase 50,000 shares of our common stock at $2.60 per share, options to purchase45,500 shares of our common stock at $2.58 per share, options to purchase 50,000 shares of our common stock at $2.96 per share, optionsto purchase 35,000 shares of our common stock at $5.49 per share, options to purchase 25,000 shares of our common stock at $18.11 pershare, options to purchase 33,333 shares of our common stock at $10.09 per share and options to purchase 16,667 shares of common stockat $8.57 per share that have vested or are vesting within 60 days. Excludes options to purchase 16,667 shares of our common stock at $10.09per share, options to purchase 50,000 shares of our common stock at $8.57 per share and options to purchase 50,000 shares of common stockat $5.36 per share that do not vest within 60 days.Â (5)Includes options to purchase 100,000 shares of our common stock at $3.28 per share, options to purchase45,500 shares of our common stock at $2.58 per share, options to purchase 50,000 shares of our common stock at $2.96 per share, optionsto purchase 35,000 shares of our common stock at $5.49 per share, options to purchase 25,000 shares of our common stock at $18.11 pershare, options to purchase 33,333 shares of our common stock at $10.09 per share and options to purchase 16,667 shares of common stockat $8.57 per share that have vested or are vesting within 60 days. Excludes options to purchase 16,667 shares of our common stock at $10.09per share, options to purchase 50,000 shares of our common stock at $8.57 per share and options to purchase 50,000 shares of common stockat $5.36 per share that do not vest within 60 days.Â 84 Â Â (6)Includes options to purchase 50,000 shares of our common stock at $1.76 per share, options to purchase100,000 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, optionsto purchase 50,000 shares of our common stock at $2.96 per share, options to purchase 35,000 shares of our common stock at $5.49 per share,options to purchase 25,000 shares of our common stock at $18.11 per share, options to purchase 33,333 shares of our common stock at $10.09per share and options to purchase 16,667 shares of common stock at $8.57 per share that have vested or are vesting within 60 days. Excludesoptions to purchase 16,667 shares of our common stock at $10.09 per share, options to purchase 50,000 shares of our common stock at $8.57per share and options to purchase 50,000 shares of common stock at $5.36 per share that do not vest within 60 days.Â (7)Includes options to purchase 50,000 shares of our common stock at $5.39 per share, options to purchase45,500 shares of our common stock at $2.58 per share, options to purchase 50,000 shares of our common stock at $2.96 per share, optionsto purchase 35,000 shares of our common stock at $5.49 per share, options to purchase 25,000 shares of our common stock at $18.11 pershare, options to purchase 33,333 shares of our common stock at $10.09 per share and options to purchase 16,667 shares of common stockat $8.57 per share that have vested or are vesting within 60 days. Excludes options to purchase 16,667 shares of our common stock at $10.09per share, options to purchase 50,000 shares of our common stock at $8.57 per share and options to purchase 50,000 shares of common stockat $5.36 per share that do not vest within 60 days.Â (8)Includes options to purchase 30,000 shares of our common stock at $3.30 per share, options to purchase30,000 shares of our common stock at $2.30 per share, options to purchase 27,300 shares of our common stock at $2.58 per share, optionsto purchase 35,000 shares of our common stock at $2.93 per share, options to purchase 70,000 shares of our common stock at $2.96 per share,options to purchase 50,000 shares of our common stock at $5.49 per share and options to purchase 10,000 shares of common stock at $10.09per share that have vested or are vesting within 60 days. Excludes options to purchase 40,000 shares of our common stock at $18.11 pershare, options to purchase 30,000 shares of our common stock at $10.09 per share, options to purchase 50,000 shares of our common stockat $8.57 per share and options to purchase 50,000 shares of common stock at $5.36 per share that do not vest within 60 days.Â (9)Based on Schedule 13G/A as filed with the SEC and dated on February 13, 2024Â (10)Based on Schedule 13G/A as filed with the SEC and dated on January 25, 2024Â Change in ControlÂ We are unaware of any contract or other arrangement, the operation of whichmay at a subsequent date result in a change of control of our Company.Â Securities Authorized for Issuance under Equity Compensation Plansor Individual Compensation Arrangements Â The following table summarizes certain information regarding our equitycompensation plan or individual compensation arrangements at September 30, 2024:Â Equity Compensation Plan Information Plan CategoryÂ Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)Â Weighted-average exercise price of outstanding options, warrants and rights (b)Â 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 holdersÂ Â 22,050,553Â Â Â 7.02Â Â Â 5,462,202Â Equity compensation plans not approved by security holdersÂ Â â€”Â Â Â â€”Â Â Â â€”Â TotalÂ Â 22,050,553Â Â Â 7.02Â Â Â 5,462,202Â Â 85 Â Â 2022 Stock Option PlanÂ On March 25, 2022, the Board approved the 2022 OmnibusIncentive Plan (the â€œ2022 Planâ€). The 2022 Plan was approved by stockholders on May 24, 2022. Under the terms of the 2022Plan, 10,000,000 shares of Common Stock were made available for issuance under the 2022 Plan, in addition to the shares available underthe 2019 Omnibus Incentive Plan (the â€œ2019 Planâ€) and the 2015 Omnibus Incentive Plan (the â€œ2015 Planâ€). Any awardsoutstanding under a previous stock option plan will remain subject to and be paid under such plan, and any shares subject to outstandingawards under a previous plan that subsequently cease to be subject to such awards (other than by reason of settlement of the awards inshares) will automatically become available for issuance under the 2022 Plan.Â The 2022 Plan provides that it may be administeredby the Board, or the Board may delegate such responsibility to a committee. The exercise price will be determined by the Board at thetime 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, thenthe exercise price shall not be less than 110% of fair market value of the Companyâ€™s shares of common stock on the grant date. Stockoptions may be granted under the 2022 Plan for an

exercise period of up to ten years from the date of grant of the option or such lesserperiods as may be determined by the Board, subject to earlier termination in accordance with the terms of the 2022 Plan.Â The purpose of the 2022 Plan is to retain the servicesof valued key employees and consultants of our Company and such other persons, and to encourage such persons to acquire a greater proprietaryinterest in our Company, thereby strengthening their incentive to achieve the objectives of the shareholders of our Company. The purposeis also to serve as an aid and inducement in the hiring of new employees and to provide an equity incentive to consultants.Â ITEM 13. CERTAIN RELATIONSHIPSAND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCEÂ Transactions with related personsÂ There have been no transactions, since October 1,2022, or currently proposed transactions, in which we were or are to be a participant and the amount involved exceeds the lesser of $120,000or one percent of the average of the smaller reporting companyâ€™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.Â i.any director or executive officer of our Company;Â ii.any beneficial owner of shares carrying more than 5% of the voting rights attached to our outstandingshares of common stock; andÂ iii.any member of the immediate family (including spouse, parents, children, siblings and in-laws) of anyof the foregoing persons.Â Compensation of Named Executive Officers andDirectorsÂ For information regarding compensation of named executiveofficers and directors, please see â€œItem 11. Executive Compensation.â€Â Director IndependenceÂ Under the NASDAQ Stock Market Rules, the Board hasa responsibility to make an affirmative determination that those members of its Board that serve as independent directors do not haveany relationships with the Company and its businesses that would impair their independence. The Board has determined that that ChristopherMissling, PhD is not independent, as that term is defined by NASDAQ 5605(a)(2), because Mr. Missling serves as our President, Chief ExecutiveOfficer, and Secretary.Â 86 Â Â The Board has determined that that Claus van der Velden,Athanasios Skarpelos, Steffen Thomas, Peter Donhauser and Jiong Ma are independent, as that term is defined by NASDAQ 5605(a)(2) and theapplicable rules of the Commission.Â ITEM 14. PRINCIPAL ACCOUNTINGFEES AND SERVICESÂ Fees Paid to Our Independent Registered PublicAccounting Firm Â The following table sets forth the aggregate feesbilled or expected to be billed to our Company for professional services rendered by our independent registered public accounting firm,Grant Thornton, LLP for the fiscal years ended September 30, 2024 and 2023: Â Â 2024Â 2023 Audit FeesÂ $446,250Â Â $444,098Â Audit Related FeesÂ Â â€”Â Â Â â€”Â Tax FeesÂ Â â€”Â Â Â â€”Â All Other FeesÂ Â â€”Â Â Â â€”Â Total FeesÂ $446,250Â Â $444,098Â Â Audit Fees. Consist of fees billed forprofessional services rendered for the audits of our financial statements, reviews of our interim financial statements included in quarterlyreports, services performed in connection with regular filings with the Commission for the fiscal years ended September 30, 2024 and 2023in connection with statutory and regulatory filings or engagements.Â Policy on Pre-Approval by Audit Committee ofServices Performed by Independent Registered Public Accounting Firm Â Our Audit Committee pre-approves all services providedby our independent registered public accounting firm. All of the above services and fees were reviewed and approved by our Audit Committee.Â Our Audit Committee has considered the nature andamount of fees billed or expected to be billed by Grant Thornton LLP and believes that the provision of services for activities unrelatedto the audit was compatible with maintaining Grant Thornton LLPâ€™s independence.Â 87 Â Â PART IVÂ ITEM 15. EXHIBITS, FINANCIALSTATEMENT SCHEDULESÂ Exhibit Number Description (3) Articles of Incorporation and Bylaws 3.1 Articles of Incorporation, as amended (incorporated by reference to our Annual Report on Form 10-K for the year ended September 30, 2021 filed on November 24, 2021) 3.2 Amended and Restated Bylaws (incorporated by reference to our Current Report on Form 8-K filed on April 14, 2023) (4) Instruments Defining the Rights of Security Holders 4.1 Description of Registrantâ€™s Securities (incorporated by reference to our Annual Report on Form 10-K filed on November 28, 2022) 4.2 Registration Rights Agreement, dated February 3, 2023, by and between the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to our Quarterly Report on Form 10-Q filed on February 7, 2023) (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, Annex B, dated February 11, 2019, as filed on February 11, 2019) 10.3^ 2022 Omnibus Incentive Plan (incorporated by reference to our Proxy Statement, dated April 11, 2022, Annex A, filed on April 11, 2022)Â 10.4^ Employment Agreement, dated as of July 5, 2013, by and between the Company and Christopher Missling, PhD (incorporated by reference to our Quarterly Report on Form 10-Q filed on August 14, 2013) 10.5^ 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) 10.6^ 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) 10.7^ 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) 10.8^ Third Amendment to Employment Agreement, dated April 7, 2022 by and between the Company and Christopher Missling, PhD (incorporated by reference to our Current Report on Form 8-K filed on April 8, 2022) 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^ Amendment No. 2 to Amended and Restated Employment Agreement between the Company and Sandra Boenisch, dated February 28, 2022 (incorporated by reference to our Current Report on Form 8-K filed on March 4, 2022) 10.12 Purchase Agreement dated February 3, 2023 by and between the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to our Quarterly Report on Form 10-Q filed on February 7, 2023)Â 88 Â Â (14) Code of Ethics 14.1 Code of Ethics Adopted on August 1, 2023 (incorporated by reference to our Annual Report on Form 10-K filed on November 27, 2023) 19.1* Insider Trading Policy (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 (32) Section 906 Certifications 32.1** Section 906 Certification of Christopher Missling, PhD and Sandra Boenisch (97) Policy Relating to Recovery of Erroneously Awarded Compensation 97.1 Anavex Life Sciences Corp. Compensation Clawback Policy (incorporated by reference to our Annual Report on Form 10-K filed on November 27, 2023) (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 104 Cover Page Interactive Data File (formatted as Inline XBRL and

contained in Exhibit 101) Â * Filed herewith.Â ** The certification attached as Exhibit 32.1 that accompaniesthis Form 10-K is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Registrant under theSecurities Act or the Exchange Act, whether made before or after the date of this Form 10-K, irrespective of any general incorporationlanguage contained in such filing.Â ^ Denotes a management contract or compensatory plan or arrangement.Â ITEM 16. FORM 10-K SUMMARYÂ Not Applicable.Â 89 Â Â SIGNATURESÂ Pursuantto the requirements of SectionÂ 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report tobe signed on its behalf by the undersigned thereunto duly authorized.Â Date: December 23, 2024ANAVEX LIFE SCIENCES CORP.Â Â Â Â By:/s/ Christopher Missling, PhDÂ Name:Christopher Missling, PhDÂ Title:Chief Executive Officer (Principal Executive Officer) Â Â Â Pursuantto the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of theregistrant and in the capacities and on the dates indicated.Â SignaturesÂ Title(s)Â DateÂ Â Â Â Â /s/ Christopher Missling, PhDÂ Â Â December 23, 2024Christopher Missling, PhDÂ Chief Executive Officer (Principal Executive Officer) and DirectorÂ Â Â Â Â Â Â /s/ Sandra BoenischÂ Â Â December 23, 2024Sandra Boenisch, CPA, CGAÂ Principal Financial Officer and Treasurer (Principal Accounting Officer)Â Â Â Â Â Â Â /s/ Jiong Ma, PhDÂ Â Â December 23, 2024Jiong Ma, PhDÂ Director, ChairÂ Â Â Â Â Â Â Â /s/ Claus van der Velden, PhDÂ Â Â December 23, 2024Claus van der Velden, PhDÂ DirectorÂ Â Â Â Â Â Â /s/Athanasios SkarpelosÂ Â Â December 23, 2024Athanasios SkarpelosÂ DirectorÂ Â Â Â Â Â Â /s/ Steffen Thomas, PhDÂ Â Â December 23, 2024Steffen Thomas, PhDÂ DirectorÂ Â Â Â Â Â Â /s/ Peter Donhauser, D.O.Â Â Â December 23, 2024Peter Donhauser, D.O.Â DirectorÂ Â Â 90Â Â Â Â EXHIBIT 19.1Â ANAVEXLIFE SCIENCES CORP.Insider Trading PolicyÂ Anavex Life Sciences Corp. (â€œAnavexâ€)has adopted this Insider Trading Policy (the â€œPolicyâ€) to promote compliance with federal securities laws by directors,officers, employees and consultants of Anavex and its affiliates, as well as any immediate family members sharing the household of anyof the foregoing (collectively, the â€œCovered Personsâ€). The Policy also is designed to protect an important corporateasset: Anavexâ€™s reputation for integrity and ethical conduct. The Policy governs transactions in securities of Anavex or any otherissuer where conflicts of interest could arise. As a result of applicable securities laws and the Policy, Covered Persons may, from timeto time, have to forego or delay a desired securities transaction, and may suffer economic loss or forego anticipated profit as a result.Â POLICYÂ No Covered Person may trade in Anavexsecurities unless certain that he or she does not possess material inside information. No Covered Person may disclose, or â€œtip,â€such information to others who might use it for trading or might pass it along to others who might trade.Â Similarly, Covered Persons may not tradein securities of any other company unless they are certain that they do not possess any material inside information about that companywhich they obtained in the course of their employment or consulting relationship with Anavex, such as information about a major contractor merger being negotiated.Â Inside informationrelating to Anavex is the property of Anavex, and the unauthorized disclosure of such information is forbidden.Â DEFINITIONSÂ Securities include common stock and derivativesecurities such as put and call options and convertible debentures or preferred stock, as well as debt securities such as bonds and notes.Â Trading includes buying or selling.It does not include purchasing stock under an employee option or making a gift that does not satisfy a legal obligation.Â Material information is any informationthat a reasonable investor would consider important in a decision to buy, sell or hold the securities. Any information that could reasonablybe expected to affect the price of the securities is likely to be considered material. Examples of material information include unexpectedfinancial results, proposed major mergers and acquisitions, sale of major assets, changes in dividends, an extraordinary item for accountingpurposes, and important business developments such as the entry or exit of a strategic relationship or discoveries or major litigation.The information may be positive or negative. The public, the media, and the courts may use hindsight in judging what is material.Â Inside means information has notyet become publicly available. Release of information to the media does not immediately free Covered Persons to trade. Covered Personsshould refrain from trading until the market has had an opportunity to absorb and evaluate the information. If the information has beenwidely disseminated, it is usually sufficient to wait at least 24 hours after publication.Â ADDITIONAL PROHIBITIONS AND GUIDANCEÂ Short Sales and Derivatives.Â Short sales of Anavex securities (a sale of securities which arenot then owned), including a â€œsale against the boxâ€ (a sale with delayed delivery) are prohibited.Â Â Â No Covered Person may ever engage in transactions in publiclytraded options, such as puts, calls and other derivative securities, relating to Anavex. This prohibition also extends tovarious forms of hedging transactions or monetization transactions, such as zero-cost collars and forward sale contracts, as theyinvolve the establishment of a short position in Anavex securities. This prohibition does not prevent employees from exercisingcompany-issued options, subject to the other restrictions of this Policy.Â Standing OrdersÂ Standing orders (except standing orders underapproved Rule 10b5-1 plans, see below) should be used only for a brief period of time. The problem with purchases or sales resultingfrom standing instructions to a broker is that there is no control over the timing of the transaction. The broker could execute a transactionwhen you are in possession of material inside information.Â Margin Accounts and PledgesÂ Securities held in a margin accountmay be sold by the broker without the customerâ€™s consent if the customer fails to meet a margin call. Similarly, securities pledgedas collateral for a loan may be sold in foreclosure if the borrower defaults on the loan or, in many instances, if the value of the collateraldeclines. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material inside information regardingAnavex, Covered Persons are prohibited from holding securities of Anavex in a margin account or pledging such securities as collateralfor a loan. An exception to this prohibition may be permitted in certain limited circumstances with the advance written approval of thePrincipal Financial Officer.Â Penalties for non-complianceÂ The following penalties apply under UnitedStates Securities and Exchange Commission (â€œSECâ€) Rule 10b-5, which prohibits trading on material inside information:(1) imprisonment of up to 20 years, (2) criminal fines of up to $5 million, (3) civil penalties of up to 3 times the profits gained orlosses avoided,Â (4)Â Â Â Â Â Â Â prejudgmentinterest, and (5) private party damages. In addition to damage to reputation, violation of this Policy could result in termination.Â 10b5-1 PlansÂ Rule 10b5-1 provides a defense from insidertrading liability under SEC Rule 10b-5. To be eligible for this defense, a Covered Person may enter into a â€œ10b5-1 planâ€ fortrading in Anavex stock. If the plan meets the requirements of Rule 10b5-1, Anavex stock may be purchased or sold without regard to certaininsider trading restrictions.Â To comply with this insider trading policy,a 10b5-1 plan must be approved by the Principal Financial Officer and meet the requirements of Rule 10b5-1.Â In general, a 10b5-1 plan must be enteredinto a time when there is no undisclosed material information. Once the plan is adopted, the Covered Person must not exercise any influenceover the amount of securities to be traded, the price at which they are to be traded or the date of the trade. The plan must either specifythe amount, pricing and timing of transactions in advance or delegate discretion on these matters to an independent third party.Â Internet and Social MediaÂ Because of the potential for

abuse ofthe prohibition on â€œtipping,â€ Covered Persons are prohibited from posting any information on Internet chat rooms, social mediaor other types of public forums where Anavex or Anavex securities are a topic.Â 2 Â Â BLACKOUT POLICYÂ As part of this Policy, Anavex has adopteda blackout policy that prohibits trading in Anavex securities by officers, directors and certain employees and/or consultants, beginningon the last day of each fiscal quarter and ending 24 hours after earnings for such quarter are publicly released.Â Who is covered by this blackout policy?Â â—All Covered PersonsÂ What transactions are prohibited duringa blackout period?Â â—Open market purchase or sale of Anavex securitiesÂ â—Purchase or sale of Anavex securities through a brokerÂ â—Exercise of stock options where all or a portionof the acquired stock is sold during the blackout periodÂ What transactions are allowed during a blackout period?Â â—Exercise of stock options where no Anavexstock is sold in the market to fund the option exerciseÂ â—Gifts of Anavex stock, unless you have reasonto believe the recipient intends to sell the shares during the current blackout periodÂ â—Transfers of Anavex stock to or from a trustÂ â—Transaction that comply with SEC Rule 10b5-1pre-arranged written plans (for further information about pre-arranged plans, please contact the Principal Financial Officer)Â In addition to the standard end-of-quarterblackout periods, Anavex may, from time to time, impose other blackout periods upon notice to those persons who are affected. The scopeof persons affected may be broader than, or different from, the persons described above.Â Covered Persons not otherwise subjectto this blackout policy are encouraged to refrain from trading Anavex securities during blackout periods to avoid the appearance of impropertrading.Â PRE-CLEARANCE OF STOCK TRANSACTIONSÂ All Covered Persons must obtain priorwritten clearance from Anavexâ€™s Principal Financial Officer, or her designee, before he or she makes any purchases or sales of Anavexâ€™sSecurities, including any exercise of stock options. Each proposed transaction will be evaluated to determine if it raises insider tradingconcerns or other concerns under the federal or state securities laws and regulations. Any advice will relate solely to the restraintsimposed by law and will not constitute advice regarding the investment aspects of any transaction. Clearance of a transaction is validonly for a 48-hour period. If the transaction order is not placed within that 48-hour period, clearance of the transaction must be re-requested. If clearance is denied, the fact of such denial must be kept confidential by the person requesting such clearance.Â SECTION 16 REPORTSÂ Some officers and all Anavex directorsare obligated to file Section 16 reports when they engage in transactions in Anavex securities. Although the Principal Financial Officerâ€™soffice will assist reporting persons in preparing and filing the required reports, the reporting persons retain responsibility for thereports.Â 3 Â Â Who is obligated to file Section 16 reports? Â â—Anavex directorsÂ â—Anavex officers designated as â€œexecutiveofficersâ€ for SEC reporting purposes by the Board of Directors.Â FORM 144 REPORTSÂ Anavex directors and certain Anavex officersdesignated by the Board of Directors are required to file Form 144 before making an open market sale of Anavex securities. Form 144 notifiesthe SEC of your intent to sell Anavex securities. This form is generally prepared and filed by your broker and is in addition to the Section16 reports filed on your behalf by the Principal Financial Officerâ€™s Office.Â Adopted: August 9, 2017Â 4Â Â Â Â EXHIBIT21.1Â SUBSIDIARIESOF THE REGISTRANTÂ Â Â Name of SubsidiaryÂ Jurisdiction of Incorporation or OrganizationAnavex Australia Pty LimitedÂ AustraliaAnavex Germany GmbHÂ GermanyAnavex Canada Ltd.Â Ontario, CanadaÂ Â Â Â Â EXHIBIT 23.1Â CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTINGFIRMÂ Â We have issued our report dated December 23, 2024, with respect to theconsolidated financial statements included in the Annual Report of Anavex Life Sciences Corp. on Form 10-K for the year ended September30, 2024. We consent to the incorporation by reference of said report in the Registration Statements of Anavex Life Sciences Corp. onForms S-3 (File No. 333-218292 and File No. 333-281089) and on Forms S-8 (File No. 333-219934, File No. 333-255166 and File No. 333-265537).Â /s/ GRANT THORNTON LLPÂ Melville, New YorkDecember 23, 2024Â Â Â Â Â EXHIBIT 31.1Â CERTIFICATIONÂ I, Christopher Missling, certify that:Â 1.Â I have reviewed this Annual Report on Form 10-K of Anavex Life Sciences Corp.; Â Â Â Â 2.Â Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report; Â Â Â Â 3.Â Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report; Â Â Â Â 4.Â The registrantâ€™s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have: Â Â Â Â Â Â a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; Â Â Â Â Â Â Â b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; Â Â Â Â Â Â Â c)Evaluated the effectiveness of the registrantâ€™s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and Â Â Â Â Â Â Â d)Disclosed in this report any change in the registrantâ€™s internal control over financial reporting that occurred during the registrantâ€™s most recent fiscal quarter (the registrantâ€™s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrantâ€™s internal control over financial reporting; and Â Â Â Â Â 5.Â The registrantâ€™s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrantâ€™s auditors and the audit committee of the registrantâ€™s board of directors (or persons performing the equivalent functions): Â Â Â Â Â Â a)All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrantâ€™s ability to record, process, summarize and report financial information; and Â Â Â Â Â Â Â b)Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrantâ€™s internal control over financial reporting. Â Â Date: December 23, 2024/s/Christopher Missling Â Â Christopher Missling, PhD Â Chief Executive Officer, President, Secretary (Principal Executive Officer)Â Â Â Â Â Â EXHIBIT 31.2Â CERTIFICATIONÂ I, Sandra Boenisch, certify that:Â 1.Â I have reviewedthis Annual Report on Form 10-K of Anavex Life Sciences Corp.; Â Â Â Â 2.Â Based on my knowledge,this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statementsmade, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by thisreport; Â Â Â Â 3.Â Based on my knowledge,the financial statements, and other financial

information included in this report, fairly present in all material respects the financialcondition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report; Â Â Â Â 4.Â The registrantâ€™sother certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined inExchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f)and 15d-15(f)) for the registrant and have: Â Â Â Â Â Â a)Designed such disclosurecontrols and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that materialinformation relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities,particularly during the period in which this report is being prepared; Â Â Â Â Â Â Â b)Designed such internal controlover financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonableassurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordancewith generally accepted accounting principles; Â Â Â Â Â Â Â c)Evaluated the effectivenessof the registrantâ€™s disclosure controls and procedures and presented in this report our conclusions about the effectiveness ofthe disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and Â Â Â Â Â Â Â d)Disclosed in this report anychange in the registrantâ€™s internal control over financial reporting that occurred during the registrantâ€™s most recent fiscalquarter (the registrantâ€™s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonablylikely to materially affect, the registrantâ€™s internal control over financial reporting; and Â Â Â Â Â 5.Â The registrantâ€™sother certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, tothe registrantâ€™s auditors and the audit committee of the registrantâ€™s board of directors (or persons performing the equivalentfunctions): Â Â Â Â Â Â a)All significant deficienciesand material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adverselyaffect the registrantâ€™s ability to record, process, summarize and report financial information; and Â Â Â Â Â Â Â b)Any fraud, whether or not material,that involves management or other employees who have a significant role in the registrantâ€™s internal control over financial reporting.Â Â Date: December 23, 2024 /s/Sandra Boenisch Â Â Sandra Boenisch, CPA, CGAÂ Principal Financial Officer, Treasurer (Principal Financial and Accounting Officer)Â Â Â Â Â Â Â EXHIBIT 32.1Â CERTIFICATION PURSUANT TO18 U.S.C. SECTION 1350AS ADOPTED PURSUANT TOSECTION 906 OF THE SARBANES-OXLEY ACT OF 2002Â In connection with the Annual Report of Anavex LifeSciences Corp. (the â€œCompanyâ€) on Form 10-K for the fiscal year ending September 30, 2024 as filed with the Securities andExchange Commission on the date hereof (the â€œReportâ€), each of the undersigned, in the capacities and on the date indicatedbelow, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, thatto the best of his or her knowledge:Â (1)The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and Â Â Â (2)The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company. Â Â Date: December 23, 2024Â Â Â Â /s/ Christopher MisslingÂ Christopher Missling, PhDÂ Chief Executive Officer, President, Secretary (PrincipalExecutive Officer)/s/ Sandra Boenisch Â Â Â Sandra Boenisch, CPA, CGAÂ Principal Financial Officer, Treasurer (Principal Financial and Accounting Officer)Â Â The foregoing certification is being furnished solelyto accompany the Report pursuant to 18 U.S.C. Â§ 1350, and is not being filed for purposes of Section 18 of the Securities ExchangeAct of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the datehereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronicversion of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnishedto the Securities and Exchange Commission or its staff upon request.Â Â Â