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

FORM 10-K

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2024

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER: 333-249434

SYNAPTOGENIX, INC.

(*Exact name of registrant as specified in its charter)*

Delaware	46-1585656
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
1185 Avenue of the Americas, 3rd Floor New York, New York	10036
(Address of Principal Executive Offices)	*(Zip Code)*

973-242-0005

(Registrant's Telephone Number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	SNPX	The Nasdaq Stock Market LLC

Securities registered pursuant to section 12(g) of the Act: None.

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.
Yes ☐ No ☒

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).
Yes ☒ No ☐

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the common stock held by non-affiliates of the registrant was $6,623,571 as of June 28, 2024 (the last business day of the registrant's most recently completed second fiscal quarter), based on the closing share price on the Nasdaq Capital Market reported for such date. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of March 27, 2025, the registrant had 1,389,815 shares of common stock outstanding.

Auditor Name:	Stephano Slack LLC	Auditor Location:	Wayne, PA	Auditor Firm ID:	03523

DOCUMENTS INCORPORATED BY REFERENCE

None.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING INFORMATION

This report contains forward-looking statements, including, without limitation, in the sections captioned "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations," and elsewhere. Any and all statements contained in this report that are not statements of historical fact may be deemed forward-looking statements. Terms such as "may," "might," "would," "should," "could," "project," "estimate," "pro-forma," "predict," "potential," "strategy," "anticipate," "attempt," "develop," "plan," "help," "believe," "continue," "intend," "expect," "future," and terms of similar import (including the negative of any of the foregoing) may be intended to identify forward-looking statements. However, not all forward-looking statements may contain one or more of these identifying terms. Forward-looking statements in this report may include, without limitation, statements regarding (i) the plans and objectives of management for future operations, including plans or objectives relating to the development of commercially viable pharmaceuticals, (ii) a projection of income (including income/loss), earnings (including earnings/loss) per share, capital expenditures, dividends, capital structure or other financial items, (iii) our future financial performance, including any such statement contained in a discussion and analysis of financial condition by management or in the results of operations included pursuant to the rules and regulations of the U.S. Securities and Exchange Commission ("SEC"), and (iv) the assumptions underlying or relating to any statement described in points (i), (ii) or (iii) above.

The forward-looking statements are not meant to predict or guarantee actual results, performance, events, or circumstances and may not be realized because they are based upon our current projections, plans, objectives, beliefs, expectations, estimates and assumptions and are subject to a number of risks and uncertainties and other influences, many of which we have no control over. Actual results and the timing of certain events and circumstances may differ materially from those described by the forward-looking statements as a result of these risks and uncertainties. Factors that may influence or contribute to the inaccuracy of the forward-looking statements or cause actual results to differ materially from expected or desired results may include, without limitation, our inability to obtain adequate financing, the significant length of time associated with drug development and related insufficient cash flows and resulting illiquidity, our inability to expand our business, significant government regulation of pharmaceuticals and the healthcare industry, lack of product diversification, volatility in the price of our raw materials, existing or increased competition, results of arbitration and litigation, stock volatility and illiquidity, and our failure to implement our business plans or strategies. A description of some of the risks and uncertainties that could cause our actual results to differ materially from those described by the forward-looking statements in this report appears in the section captioned "Risk Factors" and elsewhere in this report.

Readers are cautioned not to place undue reliance on forward-looking statements because of the risks and uncertainties related to them and to the risk factors. We disclaim any obligation to update the forward-looking statements contained in this report to reflect any new information or future events or circumstances or otherwise.

Unless the context otherwise indicates, references in this Annual Report on Form 10-K to the terms "Synaptogenix," "Neurotrope," "we," the "Company," "our," and "us" refer to Synaptogenix, Inc.

"Synaptogenix," and other trade names and trademarks of ours appearing in this Annual Report on Form 10-K are our property. This Annual Report on Form 10-K contains trade names and trademarks of other companies, which are the property of their respective owners. We do not intend our use or display of other companies' trade names or trademarks to imply an endorsement or sponsorship of us by such companies, or any relationship with any of these companies.

PART I

Item 1. Business.

Explanatory Note

From August 23, 2013 to December 6, 2020, Synaptogenix, Inc. (formerly known as Neurotrope Bioscience, Inc.) (the "Company" or "Synaptogenix") was a wholly owned subsidiary of Neurotrope, Inc. ("Neurotrope"). Neurotrope's operations were solely those of Synaptogenix. On May 17, 2020, Neurotrope announced plans for the complete legal and structural separation of Synaptogenix from Neurotrope (the "Spin-Off"). Under the Separation and Distribution Agreement between Neurotrope and Synaptogenix (the "Separation and Distribution Agreement"), Neurotrope distributed all of its equity interest in Synaptogenix to Neurotrope's stockholders. Following the Spin-Off, Neurotrope does not own any equity interest in Synaptogenix, and Synaptogenix operates independently from Neurotrope. On December 6, 2020, Neurotrope approved the final distribution ratio and holders of record of Neurotrope common stock, Neurotrope preferred stock and certain warrants as of November 30, 2020 received a pro rata distribution of all the equity interest in Synaptogenix. For more information about the Spin-Off, see "Management's Discussion and Analysis of Financial Condition and Result of Operation – Overview – Spin Off from Neurotrope, Inc." When used in this report, the terms "we," the "Company," "our," and "us" refers to Synaptogenix, Inc.

Introduction

We are a biopharmaceutical company with product candidates in pre-clinical and clinical development. We are principally focused on developing a product platform based upon a drug candidate called Bryostatin-1, which is synthesized from a natural product (bryostatin) that is isolated from a marine invertebrate organism, for the treatment of Alzheimer's disease ("AD"), which is in the clinical testing stage. We are also evaluating potential therapeutic applications of bryostatin for other neurodegenerative or cognitive diseases and dysfunctions, such as Fragile X syndrome, Multiple Sclerosis ("MS"), and Niemann-Pick Type C disease, which have undergone pre-clinical testing. We are also pursuing strategic relationships with entities possessing technologies that supplement our existing technology. We are party to a technology license and services agreement with the original Blanchette Rockefeller Neurosciences Institute (which has been known as Cognitive Research Enterprises, Inc. ("CRE") since October 2016), and its affiliate NRV II, LLC, which we collectively refer to herein as "CRE," pursuant to which we now have an exclusive non-transferable license to certain patents and technologies required to develop our proposed products.

Synaptogenix was formed for the primary purpose of commercializing the technologies initially developed by CRE for therapeutic applications for AD or other cognitive dysfunctions. These technologies have been under development by CRE since 1999 and, until March 2013, had been financed through funding from a variety of non-investor sources (which include not-for-profit foundations, the National Institutes of Health, which is part of the U.S. Department of Health and Human Services, and individual philanthropists). From March 2013 forward, development of the licensed technology has been funded principally through the Company in collaboration with CRE. Licensing agreements have been entered into with Stanford University for the use of synthetic bryostatin for neurodegenerative disease therapeutics and for the potential use of bryostatin-like compounds, called Bryologs, for certain therapeutic indications. Other platform compounds, originally developed at CRE, that share Protein Kinase C Epsilon ("PKC ε")-activating properties with bryostatin, are also being evaluated for potential therapeutic applications.

Recent Developments

Exploring Strategic Alternatives

In December 2024, we announced via press release that the board of directors of the Company (the "Board") had formed an independent special committee (the "Special Committee") to explore strategic opportunities to create and enhance value for investors, including promising drug development platforms and/or compelling new technologies and services. Management has reviewed the Company's financial position and has concluded that the Company's continuing financial strength offset by anticipated future cash burn rate and publicly traded stock as currency allows the Special Committee to evaluate potential strategic opportunities.

Reverse Stock Split

On April 24, 2023, the Company received a written notice from the Listing Qualifications Department of the Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that for the preceding 30 consecutive business days, the Common Stock did not maintain a minimum closing bid price of $1.00 per share as required by Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company received an initial grace period of 180 calendar days, or until October 23, 2023 (the "Initial Compliance Period"), to regain compliance with the Minimum Bid Price Requirement. On October 24, 2023, the Company received a second written notice from Nasdaq, notifying the Company that it had not regained compliance with the Minimum Bid Price Requirement during the Initial Compliance Period and granting the Company an additional grace period of 180 calendar days, or until April 22, 2024, to regain compliance. On April 4, 2024, the Company effected a one - for - twenty - five reverse stock split of the Common Stock (the "Reverse Stock Split") in order to regain compliance with the Minimum Bid Price Requirement.

On April 22, 2024, Nasdaq informed the Company that it had regained compliance with the Minimum Bid Price Requirement and that the matter was closed.

Results of Phase 2 Clinical Trial

On May 1, 2017, Neurotrope reported certain relevant top-line results from our Phase 2 exploratory clinical trial based on a preliminary analysis of a limited portion of the complete data set generated. A comprehensive analysis of the data from the Phase 2 exploratory trial evaluating Bryostatin-1 as a treatment of cognitive deficits in moderate to severe AD were published in the *Journal of Alzheimer's Disease*, vol. 67, no. 2, pp. 555-570, 2019. A total of 147 patients were enrolled into the study; 135 patients in the mITT population (as defined below) and 113 in the Completer population (as defined below). This study was the first repeat dose study of Bryostatin-1 in patients with late-stage AD (defined as a MMSE-2 of 4-15), in which two dose levels of Bryostatin-1 were compared with placebo to assess safety and preliminary efficacy ($p < 0.1$, one-tailed) after 12 weeks of treatment. The pre-specified primary endpoint, the SIB) (used to evaluate cognition in severe dementia), compared each dose of Bryostatin-1 with placebo at week 13 in two sets of patients: (1) the modified intent-to-treat ("mITT") population, consisting of all patients who received study drug and had at least one efficacy/safety evaluation, and (2) the "Completer" population, consisting of those patients within the mITT population who completed the 13-week dosing protocol and cognitive assessments.

These announced top-line results indicated that the 20 µg dose, administered after two weekly 20 µg doses during the first two weeks and every other week thereafter, met the pre-specified primary endpoint in the Completer population, but not in the mITT population. Among the patients who completed the protocol ($n = 113$), the patients on the 20 µg dose at 13 weeks showed a mean increase on the SIB of 1.5 versus a decrease in the placebo group of -1.1 (net improvement of 2.6, $p < 0.07$), whereas, in the mITT population, the 20 µg group had a mean increase on the SIB of 1.2 versus a decrease in the placebo group of -0.8 (net improvement of 2.0, $p < 0.134$). At the pre-specified 5 week secondary endpoint, the Completer patients in the 20 µg group showed a net improvement of 4.0 SIB ($p < .016$), and the mITT population showed a net improvement of 3.0 ($p < .056$). Unlike the 20 µg dose, there was no therapeutic signal observed with the 40 µg dose.

The Alzheimer Disease Cooperative Study Activities of Daily Living Inventory Severe Impairment version (the "ADCS-ADL-SIV") was another pre-specified secondary endpoint. The p values for the comparisons between 20 µg and placebo for the ADCS-ADL endpoint at 13 weeks were 0.082 for the Completers and 0.104 for the mITT population.

Together, these initial results after preliminary analysis of this exploratory trial, provided signals that Bryostatin-1, at the 20 µg dose, caused sustained improvement in important functions that are impaired in patients with moderate to severe AD, i.e., cognition and the ability to care for oneself. Since many of the patients in this study were already taking donepezil and/or memantine, the efficacy of Bryostatin-1 was evaluated in the top line results over and above the standard of care therapeutics.

The safety profile of Bryostatin-1 20 µg was minimally different from the placebo group, except for a higher incidence of diarrhea and infusion reactions (11% versus 2% for diarrhea and 17% versus 6% for infusion reactions). Infusion reactions were minimized with appropriate i.v. line precautions. Fewer adverse events were reported in patients in the 20 µg group, compared to the 40 µg group. Patients dosed with 20 µg had a dropout rate less than or identical to placebo, while patients dosed at 40 µg experienced poorer safety and tolerability, and had a higher dropout rate. Treatment emergent adverse events ("TEAEs") were mostly mild or moderate in severity. TEAEs, including serious adverse events, were more common in the 40 µg group, as compared to the 20 µg and placebo groups. The mean age of patients in the study was 72 years and similar across all three treatment groups.

Following presentation of the top line results in July 2017 at the Alzheimer's Association International Conference in London, a much more extensive analysis of a complete set of the Phase 2 trial data was conducted.

On January 5, 2018, Neurotrope announced that a pre-specified exploratory analysis of the comprehensive data set from our recent Phase 2 trial in patients with advanced AD found evidence of sustained improvement in cognition in patients receiving the 20 µg Bryostatin-1 regimen. As specified in the Statistical Analysis Plan ("SAP"), analysis of patients who did not receive memantine, an approved AD treatment, as baseline therapy showed greater SIB improvement. These findings suggested that this investigational drug could potentially treat Alzheimer's disease itself and help reduce and/or reverse the progression of AD, in addition to alleviating its symptoms.

Comprehensive follow-on analyses found that patients in the 20 µg treatment arm showed a sustained improvement in cognition over baseline compared to the placebo group at an exploratory endpoint week 15 (30 days after last dose at week 11). These data were observed in the study population as a whole, as well as in the Completers study group.

This follow-on analysis of the data evaluated SIB scores of patients at 15 weeks, 30 days after all dosing had been completed — a pre-specified exploratory endpoint. For the 20 µg group, patients in the mITT population (n=34) showed an overall improvement compared to controls (n=33) of 3.59 (p=0.0503) and in the Completers population (n=34) showed an overall improvement compared to controls (n=33) of 4.09 (p=0.0293). In summary, patients on the 20 µg dose showed a persistent SIB improvement 30 days after all dosing had been completed. These p-values and those below are one-tailed.

Additional analyses compared 20 µg dose patients who were on baseline therapy of Aricept versus patients off Aricept. No significant differences were observed. Another analysis compared the 20 µg dose patients who were on or off baseline therapy of memantine. The secondary analysis comparing SIB scores in non-memantine versus memantine patients found the following:

- At week 15, non-memantine patients in the mITT group treated with 20 µg (n=14) showed an SIB improvement score of 5.88, while the placebo patients (n=11) showed a decline in their SIB scores of -0.05 for an overall treatment of 5.93 from baseline (p=0.0576).

- At week 15, non-memantine patients in the Completers group treated with 20 µg (n=14) showed an SIB improvement of 6.24, while the placebo patients (n=11) showed a decline in their SIB scores of -0.12 for an overall treatment of 6.36 from baseline (p=0.0488).

- Patients taking memantine as background therapy in the 20 µg (n=20) and control (n=22) groups showed no improvement in SIB scores.

Memantine, an N-methyl-D-aspartate ("NMDA") receptor antagonist, is marketed under the brand names Namenda®, Namenda® XR, and Namzaric® (a combination of memantine and donepezil) for the treatment of dementia in patients with moderate-to-severe AD. It has been shown to delay cognitive decline and help reduce disease symptoms.

Further follow-on analyses used trend analyses (testing the dependence of treatment effect on repeated doses).

In the trend analyses, we found that the SIB values did not increase over time for the placebo patients resulting in slopes that were non-significantly different from zero (e.g. "zero-slopes"). In contrast, the SIB slopes for the 20 µg Bryostatin-1 patients who did not receive baseline memantine were found to be statistically significant (p<.001), giving a slope (95% CI) = 0.38 (0.18, 0.57) SIB points per week in the random intercept model, and a slope (95% CI) = 0.38 (0.18, 0.59) points per week in the random intercept and slope model. These results provided evidence that SIB improvement (drug benefit) increased as the number of successive Bryostatin-1 doses increased for the 20 µg patient cohort.

Confirmatory Phase 2 Clinical Trial

On May 4, 2018, Neurotrope announced a confirmatory, 100 patient, double-blinded clinical trial for the safe, effective 20 µg dose protocol for advanced AD patients not taking memantine as background therapy to evaluate improvements in SIB scores with an increased number of patients. Neurotrope engaged Worldwide Clinical Trials, Inc. ("WCT"), in conjunction with consultants and investigators at leading academic institutions, to collaborate on the design and conduct of the trial, which began in April 2018. During

July 2018, the first patient was enrolled in this study. Pursuant to a new Services Agreement with WCT dated as of May 4, 2018 (the "2018 Services Agreement"), WCT provided services relating to the trial. The total estimated budget for the services, including pass-through costs, drug supply and other statistical analyses, was approximately $7.8 million. The trial was substantially completed as of December 31, 2019. We incurred approximately $7.6 million in total expenses of which WCT has represented a total of approximately $7.2 million and approximately $400,000 of expenses were incurred to other trial-related vendors and consultants, resulting in a total savings for this trial of approximately $500,000.

On September 9, 2019, Neurotrope issued a press release announcing that the confirmatory Phase 2 study of Bryostatin-1 in moderate to severe AD did not achieve statistical significance on the primary endpoint, which was change from baseline to week 13 in the SIB total score.

An average increase in SIB total score of 1.3 points and 2.1 points was observed for the Bryostatin-1 and placebo groups, respectively, at week 13. There were multiple secondary outcome measures in this trial, including the changes from baseline at weeks 5, 9 and 15 in the SIB total score. No statistically significant difference was observed in the change from baseline in SIB total score between the Bryostatin -1 and placebo treatment groups.

The confirmatory Phase 2 multicenter trial was designed to assess the safety and efficacy of Bryostatin-1 as a treatment for cognitive deficits in patients with moderate to severe AD — defined as a MMSE-2 score of 4-15 — who are not currently taking memantine. Patients were randomized 1:1 to be treated with either Bryostatin-1 20µg or placebo, receiving 7 doses over 12 weeks. Patients on memantine, an NMDA receptor antagonist, were excluded unless they had been discontinued from memantine treatment for a 30-day washout period prior to study enrollment. The primary efficacy endpoint was the change in the SIB score between the baseline and week 13. Secondary endpoints included repeated SIB changes from baseline SIB at weeks 5, 9, 13 and 15.

On January 22, 2020, Neurotrope announced the completion of an additional analysis in connection with the confirmatory Phase 2 study, which examined moderately severe to severe AD patients treated with Bryostatin-1 in the absence of memantine. To adjust for the baseline imbalance observed in the study, a post-hoc analysis was conducted using paired data for individual patients, with each patient as his/her own control. For the pre-specified moderate stratum (i.e., MMSE-2 baseline scores 10-15), the baseline value and the week 13 value were used, resulting in pairs of observations for each patient. The changes from baseline for each patient were calculated and a paired t-test was used to compare the mean change from baseline to week 13 for each patient. A total of 65 patients had both baseline and week 13 values, from which there were 32 patients in the Bryostatin-1 treatment group and 33 patients in the placebo group. There was a statistically significant improvement over baseline (4.8 points) in the mean SIB at week 13 for subjects in the Bryostatin-1 treatment group (32 subjects), paired t-test $p < 0.0076$, 2-tailed. In the placebo group (33 subjects), there was also a statistically significant increase from baseline in the mean SIB at week 13, for paired t-test $p < 0.0144$, consistent with the placebo effect seen in the overall 203 study. Although there was a signal of Bryostatin-1's benefit for the moderately severe stratum, the difference between the Bryostatin-1 and placebo treatment groups was not statistically significant ($p=0.2727$). As a further test of the robustness of this moderate stratum benefit signal, a pre-specified trend analysis (measuring increase of SIB improvement as a function of successive drug doses) was performed on the repeated SIB measures over time (weeks 0, 5, 9, and 13). These trend analyses showed a significant positive slope of improvement for the treatment groups in the 203 study that was significantly greater than for the placebo group ($p<.01$).

Extended Confirmatory Phase 2 Clinical Trial

In connection with the additional analysis regarding the confirmatory Phase 2 clinical trial mentioned above, Synaptogenix also announced a $2.7 million award from the National Institutes of Health to support an additional Phase 2 clinical study focused on the moderate stratum for which we saw improvement in the 203 study. We are planning to meet with the Food and Drug Administration ("FDA") to present the totality of the clinical data for Bryostatin-1 upon trial completion.

On July 23, 2020, Synaptogenix executed a Services Agreement (the "2020 Services Agreement") with WCT. The 2020 Services Agreement relates to services for Synaptogenix's extended confirmatory Phase 2 Study. Pursuant to the terms of the 2020 Services Agreement, WCT provided services to enroll approximately 100 Phase 2 Study subjects. Synaptogenix initiated the first Phase 2 Study site during the third quarter of 2020 and enrollment was completed in March, 2022. On January 22, 2022, the Company executed a change order with WCT to accelerate trial subject recruitment totaling approximately $1.4 million. In addition, on February 10, 2022, the Company signed an additional agreement with a third-party vendor to assist with the increased trial recruitment retention totaling approximately $1.0 million which was subsequently canceled with no charges incurred by the Company. The updated total estimated

budget for the current trial services, including pass-through costs, was approximately $11.0 million. As noted below, Neurotrope was granted a $2.7 million award from the National Institutes of Health, which award was used to support the Phase 2 Study, resulting in an estimated net budgeted cost of the Phase 2 Study to Neurotrope of $9.3 million. Synaptogenix may terminate the 2020 Services Agreement without cause upon 60 days prior written notice.

On December 16, 2022, the Company issued a press release announcing that an extended confirmatory Phase 2 study of Bryostatin-1 in moderate to severe AD (Study #204) did not achieve statistical significance on the primary endpoint, which was change from baseline to week 13 in the SIB total score assessment obtained after completion of the second seven-dose course of treatment (week 28 of trial). An average increase in the SIB total score of 1.4 points and 0.6 points was observed for the Bryostatin-1 and placebo groups, respectively, at week 28. On March 7, 2023, the Company announced the results of its analysis of secondary endpoints and post hoc analysis from our Phase 2 study of Bryostatin-1. In the secondary endpoint analysis, changes from baseline at Weeks 9, 20, 24, 30, and 42 in the SIB (Severe Impairment Battery) total score were not statistically significant in the total patient population, and no pre-specified secondary endpoints were met with statistical significance in the low-to-moderately severe AD patient stratum. However, nearly all pre-specified secondary endpoints in the most advanced and severe AD (MMSE: 10-14) patient population, with baseline MMSE-2 (Mini-Mental State Examination, 2nd Edition) scores of 10-14, were achieved with statistical significance ($p = <0.05$, 2-tailed). Data also showed statistical significance in exploratory secondary endpoints for the MMSE-2 10-14 stratum, and post hoc analysis was positive. The Company is currently evaluating the data and determining next steps with the development of Bryostatin-1 for AD as well as for other potential indications, including in tandem with promising drug development platforms.

Other Development Projects

To the extent resources permit, we may pursue development of selected technology platforms with indications related to the treatment of various disorders, including neurodegenerative disorders such as AD, based on our currently licensed technology and/or technologies available from third party licensors or collaborators.

Nemours Agreement

On September 5, 2018, we announced a collaboration with Nemours A.I. DuPont Hospital (“Nemours”), a premier U.S. children’s hospital, to initiate a clinical trial in children with Fragile X syndrome, a genetic disorder. In addition to the primary objective of safety and tolerability, measurements will be made of working memory, language and other functional aspects such as anxiety, repetitive behavior, executive functioning, and social behavior. On August 5, 2021, the Company announced its memorandum of understanding with Nemours to initiate a clinical trial using Bryostatin-1, under Orphan Drug Status, to treat Fragile X. The Company intends to provide the Bryostatin-1 and obtain the IND, and Nemours intends to provide the clinical site and attendant support for the trial. The Company and Nemours, jointly, will develop the trial protocol. The Company estimates its total trial and IND cost to be approximately $2.0 million. As of December 31, 2024, the Company has incurred cumulative expenses associated with this agreement of approximately $100,000.

The Company has filed an IND with the FDA. The FDA has placed the development of the IND on clinical hold pending completion of further analytics relating to drug pharmacokinetics and pharmacodynamics. The Company is currently evaluating its plans to advance Fragile X development.

BryoLogyx Agreement

In connection with a supply agreement entered into with BryoLogyx Inc. (“BryoLogyx”) on June 9, 2020, we entered into a transfer agreement (the “Transfer Agreement”) with BryoLogyx. Pursuant to the terms of the Transfer Agreement, we agreed to assign and transfer to BryoLogyx all of our rights, title and interest in and to the Cooperative Research and Development Agreement (“CRADA”) with the National Cancer Institute (“NCI”), under which Bryostatin-1’s ability to modulate CD22 in patients with relapsed/refractory CD22+ disease has been evaluated to date. Under the CRADA, the parties agreed to collaborate with the NCI’s Center for Cancer Research, Pediatric Oncology Branch (“POB”) to develop a Phase I clinical trial testing the safety and toxicity of Bryostatin-1 in children and young adults with CD22 + leukemia and B-cell lymphoma. The CRADA was transferred to BryoLogyx and we assigned to BryoLogyx our IND application for CD22 currently on file with the FDA. As consideration for the transfer of the CRADA and IND, BryoLogyx has agreed to pay to us 2% of the gross revenue received in connection with the sale of bryostatin products, up to an aggregate payment amount of $1 million.

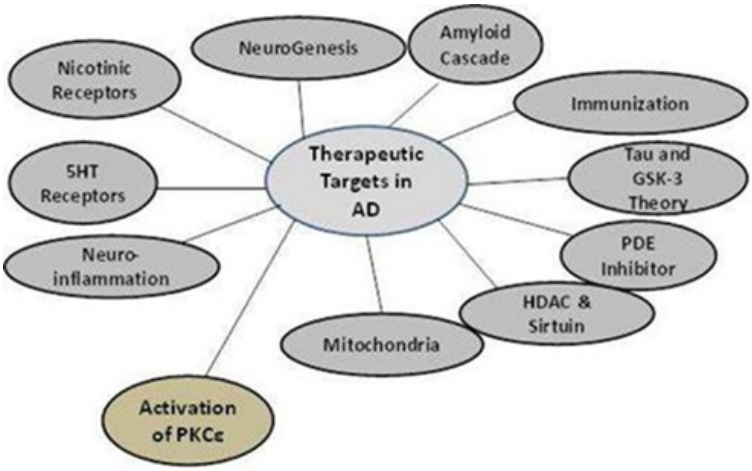
Cleveland Clinic

On February 23, 2022, the Company announced its collaboration with the Cleveland Clinic to pursue possible treatments for Multiple Sclerosis ("MS"), and on July 19, 2023, the Company announced that it had entered into an agreement with the Cleveland Clinic to conduct a Phase 1 trial of Bryostatin-1 in MS. Pursuant to the agreement, the Cleveland Clinic was obligated to manage the clinical trial's implementation, including the IND submission to the FDA which was filed during the fourth quarter of 2023 and future patient enrollment upon approval of the IND submission. The total estimated costs associated with this collaboration are approximately $2.0 million. As of December 31, 2024, the Company has paid or incurred costs with the Cleveland Clinic of approximately $528,000.

In December 2024, the Company announced via press release the termination of its agreement with the Cleveland Clinic due to the slow pace of enrollment in the Phase 1 clinical trial. The termination of the agreement was one of various actions authorized by the Board, designed to reduce cash burn rate.

Alzheimer's Disease

Figure 1. Different Pharmacologic Targets being pursued for the Treatment of AD



Business Insights: Reference Code B100040-005, Publication Date May 2011, "Advances in AD Drug Discovery"

It has been shown that during several years preceding the diagnosis of dementia associated with AD there can be gradual cognition decline, which at first may have rather benign characteristics. At this stage, known as mild cognitive impairment ("MCI"), 60% of these patients will convert to early AD. In MCI, there can already be significant loss of synapses (the junctions between nerve cells) and compromised release of the chemical messengers onto their post-synaptic targets. MCI, therefore, can transition into mild, moderate and, finally, severe stages of Alzheimer's disease that are characterized by greater systemic loss of neurons and synapses in the brain tissue. Multiple failures in acetylcholine and glutamate neurotransmitter systems (neurotransmitters) may cause some of the symptoms of early AD, and thus these systems have become targets for pharmacologic intervention.

In MCI and early AD, the amyloid load in the brain may or may not increase while the symptoms of early AD begin to occur. Loss of neurons and synaptic networks can be accompanied by abnormal processing of β amyloid ("Aβ") peptide, causing elevation of the soluble Aβ oligomers, eventually leading to the formation of Aβ plaques (protein deposits) in the brain.

The conventional amyloid cascade hypothesis holds that amyloid pathology leads to hyperphosphorylated tau proteins (a protein found in nerve cells) being deposited within neurons in the form of insoluble tangles, excitotoxicity (overstimulation of nerve

cells by neurotransmitters), inflammation and finally synaptic depletion and neuronal death. Other hypotheses suggest that AD begins earlier with dysfunctional tau metabolism — independent of amyloid levels. However, the majority of drug development efforts during the past two decades have focused on stopping the production of Aβ or its fragments, and the elimination of these peptides from either intracellular or extracellular locations has represented the preponderance of drug design efforts to halt the progression of AD. However, these efforts have been largely unsuccessful.

We believe the current failures of therapies clearing formed amyloid plaques come from an incomplete view of the AD pathophysiologic process. In our view, amyloid plaques and the tau-based neurofibrillary tangles are pathologic hallmarks of AD, but not closely correlated with cognitive deficits. Synaptic loss at autopsy, on the other hand, has been consistently closely correlated with the degree of cognitive deterioration in clinical evaluations. We believe the appearance of these plaques and tangles is not necessarily linked to the death of neurons or synapses, and that the elimination of the plaques does not restore cognitive function as already demonstrated in extensive clinical testing with pathologic correlates. However, we believe that the soluble amyloid pre-plaque oligomers, through their toxicity to synapses and neurons, are important in the progression of the disease.

Furthermore, several comprehensive studies of autopsy brain samples from AD vs. control patients have demonstrated that the loss of the synapses is an early event in AD and usually precedes the loss of neurons. (Terry et al., 1991; Scheffe et al., 2006). These studies demonstrated that the rate of cognitive decline closely correlates with the loss of synapses, while that rate does not closely correlate with the number of amyloid plaques or neurofibrillary tangles (hyperphosphorylated tau). Based on these findings, the Synaptogenix therapeutic strategy focuses on restoration of the synapses (or "synaptogenesis") and the prevention of neuronal death. Bryostatin has been shown in extensive pre-clinical testing to accomplish both synaptic restoration and prevention of neuronal death. Because these pathologic consequences are common to many neurodegenerative disorders (e.g. Fragile X mental retardation, MS, Multi-infarct dementia, and Amyotrophic Lateral Sclerosis), pre-clinical studies were undertaken by Synaptogenix scientists and scientists from other laboratories to demonstrate synaptic and neuronal loss. Based on this, common pathology therapeutic benefits of bryostatin are being clinically tested for efficacy in AD.

In animal studies, the scientific team led by our President and Chief Scientific Officer, Dr. Alkon, at CRE, found that PKC ε activation in neurons targets the loss of synapses and prevents the loss of neurons in the brains of animals with AD, and can delay or temporarily arrest other elements of the disease, e.g., by preventing: the reduction of synaptic growth factors, such as BDNF; the elevation of the toxic Aβ peptide; the appearance of plaques and tangles, and / or reversing the loss of cognitive function. In pre-clinical testing, Dr. Alkon and his teams directly demonstrated that bryostatin prevents the death of neurons (anti-apoptosis) and induces synaptogenesis by mobilizing synaptic growth factors such as BDNF, NGF, and IGF. At the same time, bryostatin appeared to prevent the formation of A Beta oligomers, prevent the deposition of amyloid plaques (extra-neuronal), prevent the formation of neurofibrillary tangles (intra-neuronal), and may restore cognitive function. These neuro-restorative benefits may result from the multi-modal molecular cascades activated by the bryostatin — PKC ε efficacies.

AD and the Potential Market for our Products

The Epidemic of AD

According to the Alzheimer's Association, it has been estimated that over 50 million people worldwide had AD, or other forms of dementia, in 2024. The prevalence of AD is independent of race, ethnicity, geography, lifestyle and, to a large extent, genetics. The most common cause of developing AD is living a long life. In developing countries where the median age of death is less than 65 years old, AD is rarely recognized or diagnosed. In the United States in 2024, 6.9 million people are estimated to have AD, and over 73% of these people are older than 75 years of age.

Researchers continue to explore a wide range of drug mechanisms in hopes of developing drugs to combat this disease. *Figure 1* illustrates the range of mechanisms under consideration. Our approach, which involves the activation of the enzyme PKC ε, represents a novel mechanism in the armamentarium of potential AD drug therapies.

Potential Market for Our Products

According to an article titled "Progress in AD" published in *The Journal of Neurology* in 2012, there has been a dearth of new product introductions in the last 20 years either for the treatment of AD symptoms or its definitive diagnosis in patients who begin exhibiting the memory and cognitive disorders associated with the disease. According to the Alzheimer's Association, all of the products

introduced to date for the treatment of AD have yielded negative or marginal results with no long-term effect on the progression of AD and no improvement in the memory or cognitive performance of the patients receiving these therapies. With over 30 million people worldwide estimated to have had AD in 2024, there is significant commercial potential for a new therapeutic that is effective in delaying the progression of the disease.

We believe the markets for drugs or therapies to treat the underlying pathology of AD exist largely, but not exclusively, in the developed world and principally comprise the North American, European and Japanese markets.

Sales of the major drug therapies available only by prescription are approved for the symptomatic treatment of the cognitive aspects of AD, but have no meaningful effect on disease progression, causing only temporary improvement in cognitive decline. Despite their limited efficacy, this group of drugs had a collective, worldwide sales compounded annual growth rate from 2017 to 2021 of 6.5% in 2022 according to Future Markets Insights. Sales were approximately $2.8 billion and are projected to grow to approximately $6.8 billion by 2032, a compounded annual growth rate of 9.3%, according to Coherent Market Insights.

Our Proposed Products

Challenges in Treating AD

One of the challenges in treating AD is that its symptoms manifest only years after the disease process can be definitely diagnosed. Treatment strategies attempting to intervene once symptoms become more apparent are focused on stimulating the neurotransmitter activity of still healthy neurons, or removing the amyloid plaque deposited in the brain. Many drug development efforts to date that have targeted the removal of beta-amyloid or tau protein as their therapeutic mechanism of action have failed, and drugs approved for stimulating neurotransmitter activity offer short-lived, palliative results for AD patients. As such, these strategies have yielded negative or marginal results with no effect on the progression of AD and no improvement in the memory or cognitive performance of the patients receiving these therapies.

Dying neurons and synapses have, to date, not been therapeutic targets for restoration, and many in the AD field currently believe that stemming the progression of the disease may only be possible with very early-stage intervention. The FDA is encouraging the pharmaceutical industry to increase efforts to investigate such early-stage interventional treatments by recommending that modified clinical endpoints, both functional and cognitive, be established to monitor the efficacy of drug prototypes being tested in early stage AD patients, according to an article titled “Drug Development of Early AD” published in The New England Journal of Medicine (NEJM.org: The New England Journal of Medicine, March 15, 2013, page 1: Drug Development of Early AD, N. Kozauer, M.D., and Russell Katz, M.D.)

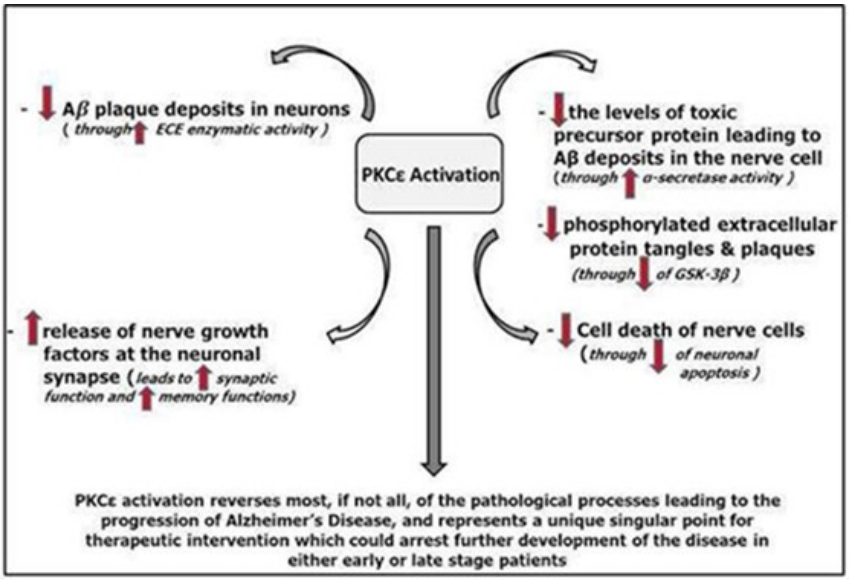
In contrast, we believe that our data from various preclinical animal models and compassionate use trials support that activation of PKC ε – BDNF pathway in central nervous system neurons may improve neuronal vitality and function in areas of the brain damaged by AD, potentially resulting in the improvement of memory and cognition.

In recent years, two therapeutic trials with monoclonal antibodies (aduhelm and lecanemab) have provided evidence of some showing of the rate of decline for patients with mid cognitive impairment (MCI) and possibly very early AD. This slowing of the rate of decline (24 – 27%) occurred after 18 months of treatment with i.v. infusions with the antibodies.

Synaptogenesis

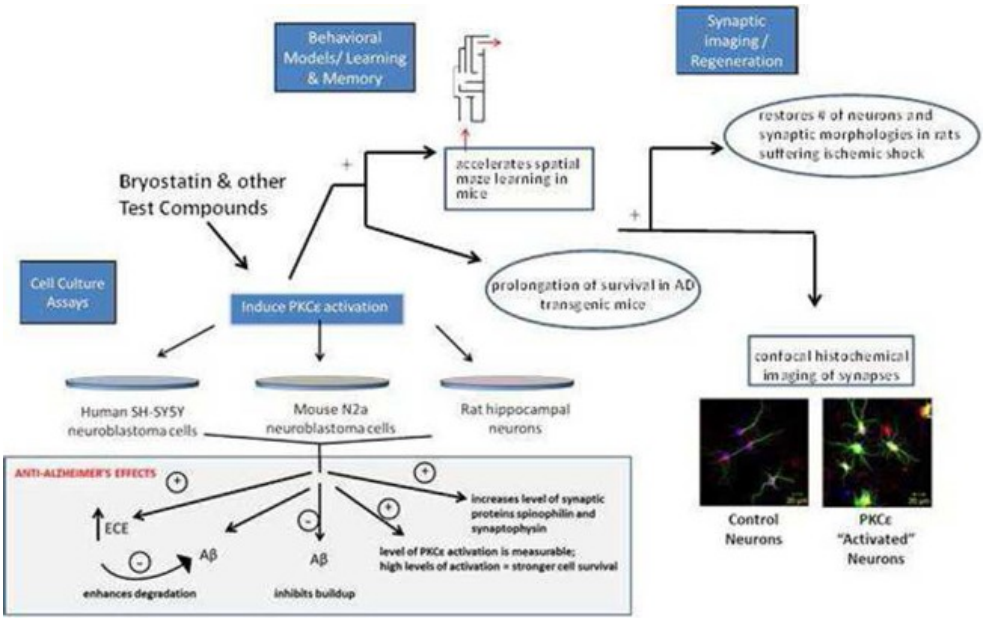
Studies of autopsy brains of AD versus control patients showed that deficient activity or low concentrations of PKC ε in aging subjects is one of the main causes of the neurodegeneration seen in AD. These deficiencies result in the loss of BDNF, an important synaptic growth factor as demonstrated by other pre-clinical and clinical research. The schematic in *Figure 2* illustrates only a portion of the changes mediated by PKC ε, and how it may help reverse the neuronal damage and loss central to the pathogenic process in AD.

Figure 2. PKC ε Activation Involves Five Different Mechanisms to Stop the Progression of AD



Activation of PKC ε has been achieved with drug prototypes that mimic the activity of diacylglycerol and phosphatidylserine, which are the natural binding targets for this enzyme. In addition, a variety of in vitro and in vivo animal models have demonstrated that these drug prototypes may be effective in restoring the structure and function of neuronal synapses. Our first clinical application of the PKC ε activators is focused on the treatment of AD, but a number of other neurodegenerative diseases may be amenable to similar treatment. A list of these potential future drug targets is shown in *Figure 3*.

Figure 3. Therapeutic targets for neuroregeneration through PKC ε activation



Treatment of AD by Stimulating Synaptic Regeneration and Prevention of Neuronal Death

Dr. Alkon's team at CRE conducted research in synaptic regeneration and the prevention of neuronal death, outside the conventional wisdom that has dominated research efforts in the industry. The pathology of AD likely has multiple layers in its development, in addition to the presence of tau phosphorylated tangles and Aβ oligomers. However, once this process presents clinical manifestations of AD, restoring synaptic function thus far has not been effectively achieved by removing Aβ plaques with experimental drug interventions. Once neurons undergo toxic changes with soluble Aβ oligomers, the loss of function to the patient has been irreversible.

CRE's and our approach has been to restore general viability and hence synaptic function in still-functioning neurons by stimulating the regeneration and growth of the dendritic branches, spines, and pre-synaptic terminals on these neurons. Dendrites are the branched projections of a neuron that act to propagate the electrochemical stimulation received from other neural cells. This process can be visualized with serial sections using an electron microscope in the brains of rats whose neurons and synapses have been damaged by ischemic shock (depriving oxygen) or traumatic injury to the brain. The morphology of the damaged neurons in these animal models looks strikingly different after they are treated with experimental drugs that activate PKC ε. The new growth of dendritic trees on the damaged neurons and the creation of a multiplicity of new synaptic connections, basically re-wiring the damaged neurons and restoring their function. Earlier therapeutic intervention with a PKC ε activator produces markedly improved outcomes in tests measuring restored animal cognitive function.

PKCε Activation Stimulates the Formation of New Synaptic Connections

The new synaptic connections formed from the damaged neurons revitalized by PKC ε in rats can be demonstrated in various behavioral models for the animals that are used to measure memory functions.

Treatment with Bryostatin-1, for 12 weeks in genetically modified rodents pre-disposed to develop an AD-type of pathology showed that Bryostatin-1 promoted the growth of new synapses and preserved the existing synapses. In addition, this drug also reversed the decrease of PKC ε and the reciprocal increase of soluble amyloid. (Journal of Neuroscience 2011, 31 (2), 630, D. Alkon et al.)

In cell tissue cultures, there is a difference in morphology between neurons damaged by the application of ASPD (soluble oligomers of Aβ) as compared to synapses rejuvenated by the application of Bryostatin-1. Treatment with Bryostatin-1, through PKC ε activation, stimulates the revitalization of neurons and the formation of new synaptic connections.

The Central Role of PKC ε in Maintaining Neuron Structure and Function

Upon activation, PKC ε migrates from the intraneuronal cytoplasm to the cell membrane, where it activates signal-regulating enzymes (specifically the m-RNA stabilizing protein, HUD, and downstream growth factors such as BDNF, NGF, IGF, etc.; MAP kinases Erk1/2; the BCl-2 apoptosis cascade; and NF- ϰϰϰϰβ), causing a series of changes leading to increased DNA transcription, synaptic maturation, a consequent increase in levels of growth factor proteins (such as nerve growth factor and brain-derived neurotrophic factor), an inhibition of programmed cell-death and a reduction of β amyloid, and hyperphosphorylated tau.

This myriad of events is orchestrated by PKC ε and prompts a number of secondary events to occur in both the pre- and post-synaptic portions of the neuron. Cellular visualization of this effect shows an increase in the number of pre-synaptic vesicles in the neurons, an increase in pre-synaptic levels of PKC ε and an increase in the number of mushroom spines associated with individual synaptic boutons (knoblike enlargements at the end of a nerve fiber, where it forms a synapse). Their genesis in these neurons is responsible for the formation of new synapses during associative learning and memory, and for regeneration of synaptic networks in pre-clinical models of AD, stroke, traumatic brain injury, and Fragile X syndrome.

The central role of PKC ε activation in these dynamic events expands the amyloid and tau hypotheses for AD by including pathways to restore the synaptic networks lost during neurodegeneration and to prevent further loss as well as to prevent neuronal loss. This mechanistic framework offers new targets for therapeutic intervention which not only prevent the formation of tangles and plaque, but also prevents neuronal death, and promotes the induction of new, mature synaptic networks.

Decreased amyloid formation from PKC ε activation results from an increase in the rate of Aβ degradation by ECE (endothelin converting enzyme) neprilysin and IDE (insulin-degrading enzyme), and induction of α-secretase cleavage of amyloid precursor protein (the precursor molecule to Aβ) through phosphorylation of an enzyme known as Erk. In rodent models genetically predisposed to forming large amounts of amyloid deposits in their brains, PKC ε activation was found to interrupt the ongoing formation of amyloid, suggesting that this approach may delay the progression of AD.

The key to CRE's innovation in this area has been in identifying highly potent drug prototypes that, at low concentrations, cause the specific and transient activation of PKC ε, without interacting with the other isozyme variants of PKC whose inactivation would negate the synaptogenic properties of the ε isoform.

Testing PKC ε Activation in Humans

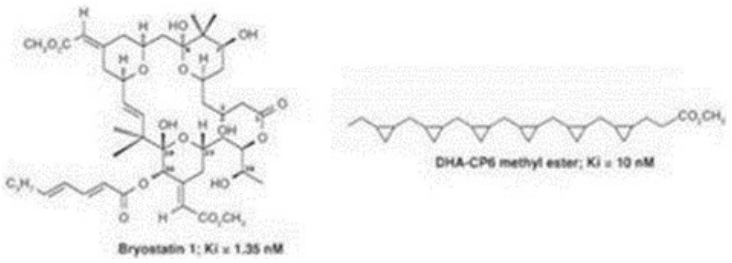
The basic drug mechanism invoking PKC ε activation for neuronal rejuvenation and synaptic regeneration has never been evaluated in humans for any drug class or therapeutic application. We believe that the pre- clinical and clinical research in this field as described above is an ideal platform for testing this approach in human subjects.

We have licensed a body of biomedical research from CRE that is comprised of new methods and drug prototypes designed to stimulate synaptic restoration. For additional information, see " —Intellectual Property—Technology License and Services Agreement." We believe the commercial application of this technology has potential to impact AD as well as traumatic brain injury, ischemic stroke, post-traumatic stress syndrome and other degenerative learning disorders.

Drug Prototypes That Treat AD Through Regeneration

CRE has developed a new chemical family of polyunsaturated fatty acid ("PUFA") analogs, which appear to be effective in the activation of PKC ε. Representative structures of Bryostatin-1 and a PUFA analog are shown in *Figure 4*.

Figure 4. Structures of Bryostatin-1 and a PUFA Analog Effective in the Activation of PKC



Ki values = effective concentration of the drug in achieving 50% activation of PKC ε

Trends in Biochemical Sciences V. 34, #3, p.136. T.J. Nelson et al, "Neuroprotective versus Tumorigenic protein kinase C activators."

These molecules activate PKC ε by binding to two different and distinct active sites on the enzyme. The natural ligands that bind to these sites are diacylglycerol and phosphatidylserine. Bryostatin-1 acts as a mimetic (mimic) for diacylglycerol by binding to the diacylglycerol site and, similarly, the PUFA analogs act as mimetics for phosphatidylserine by binding to the phosphatidylserine site.

Collaborative Agreements

Stanford License Agreements

On May 12, 2014, the Company entered into a license agreement (the "Stanford Agreement") with The Board of Trustees of The Leland Stanford Junior University ("Stanford"), pursuant to which Stanford has granted to the Company a revenue-bearing, world-wide right and exclusive license, with the right to grant sublicenses (on certain conditions), under certain patent rights and related technology for the use of bryostatin structural derivatives, known as "bryologs," for use in the treatment of central nervous system disorders, lysosomal storage diseases, stroke, cardio protection and traumatic brain injury, for the life of the licensed patents. The Company is required to use commercially reasonable efforts to develop, manufacture and sell products ("Licensed Products") in the Licensed Field of Use (as defined in the Stanford Agreement) during the term of the licensing agreement which expires upon the termination of the last valid claim of any licensed patent under this agreement. The Company is obligated to pay $10,000 annually as a license maintenance fee. In addition, the Company must meet specific product development milestones, and upon meeting such milestones, make specific milestone payments to Stanford. The Company must also pay Stanford royalties of 3% of net sales, if any, of Licensed Products (as defined in the Stanford Agreement) and milestone payments of up to $3.7 million dependent upon stage of product development. As of December 31, 2024, no royalties nor milestone payments have been required.

On January 19, 2017, the Company entered into a second license agreement with Stanford, pursuant to which Stanford has granted to the Company a revenue-bearing, world-wide right and exclusive license, with the right to grant sublicenses (on certain conditions), under certain patent rights and related technology for the use of "Bryostatin Compounds and Methods of Preparing the Same," or synthesized bryostatin, for use in the treatment of neurological diseases, cognitive dysfunction and psychiatric disorders, for the life of the licensed patents. The Company paid Stanford $70,000 upon executing the license and is obligated to pay an additional $10,000 annually as a license maintenance fee. In addition, based upon certain milestones that include product development and commercialization, the Company will be obligated to pay up to an additional $2.1 million and between 1.5% and 4.5% royalty payments on certain revenues generated by the Company relating to the licensed technology. On November 9, 2021, the Company revised the existing licensing agreement with Stanford. The revisions extended all the required future product development and commercialization

milestones. The Company is currently in full compliance with the revised agreement and is moving forward on its commitments. As of December 31, 2024, no royalties nor milestone payments have been earned or made.

The Company has advanced the development of synthetic bryostatin by demonstrating the equivalence of the synthetic to the natural bryostatin product. The estimated cost to initiate and produce sufficient quantities of the synthetic bryostatin drug product is approximately $1.5 million. The Company is evaluating production alternatives at this time.

Stanford retains the right, on behalf of itself and all other non-profit research institutions, to practice the licensed patents and use the licensed technology for any non-profit purpose, including sponsored research and collaborations. The license is also subject to Title 35, Sections 200-204, of the United States Code, which governs patent rights in inventions made with U.S. government assistance. Among other things, these provisions provide the United States government with nonexclusive rights in the licensed patents. They also impose the obligation that products based on the licensed patents sold or produced in the United States be "manufactured substantially in the United States." As discussed previously, this license agreements has been amended by a mutual agreement in November, 2021.

Mt. Sinai License Agreement

On July 14, 2014, we entered into an Exclusive License Agreement (the "Mount Sinai Agreement") with the Icahn School of Medicine at Mount Sinai ("Mount Sinai"). Pursuant to the Mount Sinai Agreement, Mount Sinai granted us (a) a revenue-bearing, world-wide right and exclusive license, with the right to grant sublicenses (on certain conditions), under Mount Sinai's interest in certain joint patents held by the Company and Mount Sinai (the "Joint Patents") as well as in certain results and data (the "Data Package") and (b) a non-exclusive license, with the right to grant sublicenses on certain conditions, to certain technical information, both relating to the diagnostic, prophylactic or therapeutic use for treating diseases or disorders in humans relying on activation of Protein Kinase C Epsilon ("PKC ε"), which includes Niemann-Pick Disease (the "Mount Sinai Field of Use"). The Mount Sinai Agreement allows us to research, discover, develop, make, have made, use, have used, import, lease, sell, have sold and offer certain products, processes or methods that are covered by valid claims of Mount Sinai's interest in the Joint Patents or an Orphan Drug Designation Application covering the Data Package ("Mount Sinai Licensed Products") in the Mount Sinai Field of Use (as such terms are defined in the Mount Sinai Agreement).

The Company is required to pay Mt. Sinai milestone payments of $2.0 million upon approval of a new drug application ("NDA") in the United States and an additional $1.5 million for an NDA approval in the European Union or Japan. In addition, the Company is required to pay Mt. Sinai royalties on net sales of licensed product of 2.0% for up to $250 million of net sales and 3.0% of net sales over $250 million. Since inception, the Company has paid Mt. Sinai approximately $210,000 consisting of licensing fees of $135,000 plus development costs and patent fees of approximately $75,000. As of December 31, 2024, no royalties nor milestone payments have been required.

Strategic Investment

On October 31, 2023, we entered into a share purchase agreement (the "Cannasoul Purchase Agreement") with Cannasoul Analytics Ltd. ("Cannasoul"), pursuant to which the Company agreed to purchase from Cannasoul (i) 12,737 shares of Cannasoul's Series A preferred shares, no par value per share (the "Cannasoul Preferred Shares"), at a price of $44.1550 per Cannasoul Preferred Share and (ii) a convertible preferred note in an aggregate amount of up to $1,437,598.49 (the "Initial Convertible Note") in a private placement (the "Cannasoul Investment"). Additionally, the Company agreed to purchase up to four additional convertible preferred notes in a total amount of up to approximately $2,000,000 (or approximately $500,000 per convertible preferred note), subject to Cannasoul achieving certain revenue and expense goals (the "Milestones") over the four quarters following signing of the Cannasoul Purchase Agreement (the "Milestone Convertible Notes") as set forth in the Cannasoul Purchase Agreement. If Cannasoul fails to achieve a Milestone, the Company will not be obligated to purchase the applicable Milestone Convertible Note. If Cannasoul achieves a Milestone and the Company fails to purchase the applicable Milestone Convertible Note, Cannasoul will have the right to convert all the Company's Cannasoul Preferred Shares into Cannasoul's ordinary shares and the Company will lose certain board appointment rights and certain rights in Cannasoul's subsidiaries, each as further described below. As of December 31, 2024, Cannasoul had achieved two Milestones and we accordingly purchased two Milestone Convertible Notes for an aggregate of $500,000 and $500,000, respectively, in January and June 2024.

Dr. David (Dedi) Meiri, founder of Cannasoul, heads the Laboratory of Cancer Biology and Cannabinoid Research at the Technion – Israel Institute of Technology ("Technion"), where he develops cannabinoids for various indications. Pursuant to a license agreement between Cannasoul, Dr. Meiri and Technion, Cannasoul has a right of first look with respect to each new cannabinoid

indication developed in Dr. Meiri's laboratory and not otherwise funded by a third party. Whenever Cannasoul exercises this right of first look, it creates a new subsidiary to carry out the development of such indication (each, a "Project Subsidiary"). In connection with the Investment, the Company received certain rights in existing Project Subsidiaries. Additionally, Cannasoul granted the Company a right of first look to invest in any new Project Subsidiaries as well as certain preemptive and veto rights in connection with such Project Subsidiaries. Pursuant to a collaboration agreement entered into by the Company and Cannasoul on October 31, 2023 (the "Collaboration Agreement"), the parties agreed to form a joint research committee with equal representation from the Company and Cannasoul (the "JRC"). The JRC will evaluate the technology and compounds developed by Dr. Meiri in his laboratory, assess the feasibility of developing and commercializing each compound and, for those compounds with respect to which we exercise our right of first look, collaborate on the strategy for clinical development of such compounds.

In connection with the Cannasoul Investment, Cannasoul adopted amended and restated articles of incorporation (the "Cannasoul Charter"). Pursuant to the Cannasoul Charter, we have a number of rights as investor, including but not limited to (i) the right to appoint and dismiss three of the seven members of Cannasoul's board of directors and veto power with respect to a fourth member, (ii) preemptive rights to participate pro rata in any pre-initial public offering financings by Cannasoul, (iii) rights of first refusal with respect to transfers of Cannasoul ordinary shares by other investors, (iv) rights of co-sale with respect to proposed sales or transfers of Cannasoul ordinary shares by certain key investors, (v) veto rights with respect to certain major transactions, any amendment to the Cannasoul Charter, approval of Cannasoul's budget and other items.

Also on October 31, 2023, we entered into an investor rights agreement (the "Investor Rights Agreement") with Cannasoul, the founders of Cannasoul and certain investors in Cannasoul. Pursuant to the Investor Rights Agreement, if Cannasoul ever completes an initial public offering in the United States, we and certain other investors in Cannasoul may, subject to conditions set forth in the Investor Rights Agreement, request that Cannasoul file a registration statement with the U.S. Securities and Exchange Commission covering the resale of the ordinary shares underlying the Cannasoul Preferred Shares.

As of December 31, 2024, the Company determined that its investment in Cannasoul had a valuation of $0 based upon its disposition of its assets and limited minority ownership in other related technologies. As a result, the Company has written off its related debt and equity investments.

Bryostatin-1

Our lead product candidate is Bryostatin-1. Bryostatin is a natural product isolated from a marine invertebrate organism, a bryozoan called *Bugula neritina*. Several total syntheses of this complex molecule have been achieved in recent years in various academic chemistry laboratories, and these approaches represent a possible alternative source of this drug. Importantly, we have an exclusive license for neurologic disorders to a new, accelerated synthesis of Bryostatin-1 recently developed at Stanford University by Dr. Paul Wender and his team. Bryostatin-1 is a PKC α and ε activator that was originally developed as a potential anticancer drug. According to Clinical Cancer Research, this drug candidate was previously evaluated in 63 clinical studies involving more than 1,400 patients at the NCI for the treatment of various forms of cancer. While having failed these studies as an experimental anti-cancer therapy, much useful information on the safety, pharmacodynamics and toxicity of the drug was obtained from these in-human trials. In general, Bryostatin-1 was considered to be "well-tolerated" in these anti-cancer trials.

It was discovered that at doses at lower levels than those used in these anticancer trials, bryostatin is a potent activator of PKC ε and may have efficacy in treating AD. As described above, activation of PKC ε has been shown to partially restore synaptic function in neurons damaged by AD in in vitro and in vivo animal models.

The NCI has entered into a material transfer agreement with CRE to provide the bryostatin required for pre-clinical research as well as the Phase 2 clinical trials planned by the Company. Our license agreement with CRE permits our access to new bryostatin clinical trial data and information held by the NCI, as well as past clinical, safety and toxicity data compiled by the NCI during the time this drug was being evaluated for its anticancer properties. See "—Intellectual Property—Technology License and Services Agreement" and "Item 1A. Risk Factors—We are partly dependent upon the NCI to supply bryostatin for our clinical trials."

CRE previously conducted an exploratory evaluation of bryostatin on a compassionate use basis in AD patients who have an inherited form of AD, frequently called familial AD, under an FDA-approved study protocol. Familial AD results from one of four major mutations in the genome, and this mutation is passed on from generation to generation within a family that carries the defective

gene. The tragic consequence of familial AD is that it strikes its victims at an early age, often while they are in their twenties. The aggressive progression of familial AD can render these patients in the terminal stages of AD in their late 30's and early 40's.

PUFA Analogs

Several other drug prototypes termed the "PUFA analogs" have been synthesized at CRE and evaluated for their PKC ε activating properties in models of AD. The PUFA analogs are not structurally related to bryostatin and activate PKC ε at a different site. We believe the PUFA analogs may represent a potential source for follow-on drug candidates. PKC ε activators from the PUFA family of drug prototypes have demonstrated neuroregeneration efficacy roughly equivalent to and, in some cases, potentially superior to that of bryostatin. If the PUFA analogs show adequate potency in preclinical models of AD, we may advance a drug prototype from this chemical family.

Other Potential Products

We may acquire, by license or otherwise, other development stage products that are consistent with our product portfolio objectives and commercialization strategy. See "—Recent Developments—Exploring Strategic Alternatives."

WCT Services Agreements

On July 23, 2020, the Company entered into the 2020 Services Agreement with WCT. The 2020 Services Agreement related to services for the current Phase 2 clinical trial assessing the safety, tolerability and long-term efficacy of Bryostatin-1 in the treatment of moderately severe AD subjects not receiving memantine treatment (the "2020 Study"). On January 22, 2022, the Company executed a change order with WCT to accelerate trial subject recruitment for which costs totaled approximately $1.4 million. In addition, on February 10, 2022, the Company signed an additional agreement with a third-party vendor to assist with the increased trial recruitment retention with costs totaling approximately $1.0 million which was subsequently canceled with no charges incurred by the Company. In addition, on September 11, 2023, the Company signed an agreement with WCT to assist with documenting the trial results which costs totaled approximately $300,000. The updated total estimated budget for these trial services, including pass-through costs, was approximately $11.3 million. As noted below, Neurotrope was granted a $2.7 million award from the National Institutes of Health, which award was used to support the Phase 2 Study, resulting in an estimated net budgeted cost of the Phase 2 Study to Neurotrope of $8.6 million.

The Company was awarded a $2.7 million grant from the NIH, which will be used to support the 2020 Study, resulting in an estimated net budgeted cost of the 2020 Study to the Company of $8.3 million. The NIH grant provided for funds of approximately $1.0 million in the first year, which began in April 2020, and funds of approximately $1.7 million in the second year, which began April 2021. As of February 22, 2022, virtually all of the NIH grant had been received and offset against the clinical trial costs. The Company incurred approximately $11.2 million of cumulative expenses associated with the current Phase 2 clinical trial as of December 31, 2023 and incurred $0 of expenses in 2024. Of the total $11.2 million incurred for the trial as of December 31, 2023, approximately $0 and $560,000 million is reflected in the statement of comprehensive loss for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, $0 of WCT prepayments are included as a prepaid expense and other current assets in the Company's balance sheet and $0 is included in accounts payable and accrued expenses.

Intellectual Property

Technology License and Services Agreement

On February 4, 2015, we, CRE and NRV II, LLC entered into an Amended and Restated Technology License and Services Agreement (the "CRE License"), which further amended and restated the Technology License and Services Agreement dated as of October 31, 2012, as amended by Amendment No. 1 dated as of August 21, 2013.

Pursuant to the CRE License, we maintained our exclusive (except as described below), non-transferable (except pursuant to the CRE License's assignment provision), world-wide, royalty-bearing right, with a right to sublicense (in accordance with the terms and conditions described below), under CRE's and NRV II's respective right, title and interest in and to certain patents and technology owned by CRE or licensed to NRV II, LLC by CRE as of or subsequent to October 31, 2012 to develop, use, manufacture, market, offer for sale, sell, distribute, import and export certain products or services for therapeutic applications for AD and other cognitive

dysfunctions in humans or animals (the "Field of Use"). Additionally, the CRE License specifies that all patents that issue from a certain patent application, shall constitute licensed patents and all trade secrets, know-how and other confidential information claimed by such patents constitute licensed technology under the CRE License. Furthermore, on July 10, 2015, under the terms of the Statement of Work and Account Satisfaction Agreement dated February 4, 2015, our rights relating to an in vitro diagnostic test system reverted back to CRE and, accordingly, we no longer have any rights under the CRE License for diagnostic applications using the CRE patent portfolio or technology.

Notwithstanding the above license terms, CRE and its affiliates retain rights to use the licensed intellectual property in the Field of Use to engage in research and development and other non-commercial activities and to provide services to us or to perform other activities in connection with the CRE License.

Under the CRE License, we and CRE may not enter into sublicense agreements with third parties except with CRE's prior written consent, which consent shall not be commercially unreasonably withheld. Furthermore, the CRE License dated February 4, 2015 revises the agreement that was entered into as of October 31, 2012 and amended on August 21, 2013, in that it provides that any intellectual property developed, conceived or created in connection with a sublicense agreement that we entered into with a third party pursuant to the terms of the CRE License will be licensed to CRE and its affiliates for any and all non-commercial purposes, on a worldwide, perpetual, non-exclusive, irrevocable, non-terminable, fully paid-up, royalty-free, transferable basis, with the right to freely sublicense such intellectual property. Previously, the agreement had provided that such intellectual property would be assigned to CRE.

Under the CRE License, we and CRE will jointly own data, reports and information that is generated on or after February 28, 2013, pursuant to the license agreement dated October 31, 2012 and amended on August 21, 2013, by us, on behalf of us by a third party or by CRE pursuant to a statement of work that the parties enter into pursuant to the CRE License, in each case to the extent not constituting or containing any data, reports or information generated prior to such date or by CRE not pursuant to a statement of work (the "Jointly Owned Data"). CRE has agreed not to use the Jointly Owned Data inside or outside the Field of Use for any commercial purpose during the term of the CRE License or following any expiration of the CRE License other than an expiration that is the result of a breach by us of the CRE License that caused any licensed patent to expire, become abandoned or be declared unenforceable or invalid or caused any licensed technology to enter the public domain (a "Natural Expiration") provided, however, CRE may use the Jointly Owned Data inside or outside the Field of Use for any commercial purpose following any termination of the CRE License. Also, CRE granted us a license during the term and following any Natural Expiration, to use certain CRE data in the Field of Use for any commercial purposes falling within the scope of the license granted to us under the CRE License.

The CRE License further requires us to pay CRE (i) a fixed research fee equal to a pro rata amount of $1 million in the year during which we close on a Series B Preferred Stock financing resulting in proceeds of at least $25 million, (ii) a fixed research fee of $1 million per year for each of the five calendar years following the completion of such financing and (iii) an annual fixed research fee in an amount to be negotiated and agreed upon no later than 90 days prior to the end of the fifth calendar year following the completion of such financing to be paid with respect to each remaining calendar year during the term of the CRE License. This fixed research fee is not yet due as the Company has not completed a Series B Preferred Stock financing in excess of $25 million. The CRE License Agreement also requires the payment by us of royalties ranging between 2% and 5% of our revenues generated from the licensed patents and other intellectual property, dependent upon the percentage ownership that Neuroscience Research Ventures, Inc. ("NRV, Inc.") holds in our company, which currently would be a royalty rate of 5% based on NRV, Inc.'s current ownership in us.

Pursuant to the terms of the November 12, 2015 amendment to the CRE License, we paid an aggregate of approximately $348,000 to CRE following the closings of the previous Series B private placement, which constituted an advance royalty payment to CRE and will be offset (with no interest) against the amount of future royalty obligations payable until such time that the amount of such future royalty obligations equals in full the amount of the advance royalty payments made, which shall be subtracted from the gross proceeds to determine the "Post-PA Fee Proceeds."

On November 29, 2018, we entered into a Second Amendment to the CRE License, pursuant to which (i) we agreed to pay all outstanding invoices and accrued expenses associated with the licensed intellectual property and (ii) the parties agreed that CRE would no longer have the right, and we would have the sole and exclusive right, to apply for, file, prosecute, and maintain patents and applications for the licensed intellectual property.

Our Licensed Intellectual Property

We have licensed from CRE an extensive intellectual property portfolio that includes issued patents, pending patent applications and provisional patent applications, in the U.S. and elsewhere, which, we believe, together cover these key pharmaceutical markets. A method of use patent has been issued to CRE that covers the use of the PUFA family of molecules for the same therapeutic applications.

We believe the CRE License provides us rights to the patents and technologies required to develop our proposed products. The patents and technologies licensed to us pursuant to the CRE License include, without limitation, the following:

- therapies based on bryostatin and PUFA chemical families; and
- methods for treating AD.

A number of CRE's patent applications for treatment of neurological disorders have been under active prosecution for many years and have been the subject of multiple rejections for anticipation and/or obviousness based on prior art. There are no guarantees that CRE's pending patent applications will issue into commercially meaningful patents. If these patent applications are not approved or successfully prosecuted, then we will attempt to seek other means of protecting its proprietary position including, but not limited to, trade secrets, proprietary formulations and methods, etc.

A substantial amount of in-human data exists that was generated by the NCI that involves the earlier evaluation of bryostatin as an anticancer agent. The NCI also holds the existing inventory of bryostatin suitable for use in humans. Our use of the substantial data package generated by the NCI on bryostatin, as well as access to the clinical supply of this substance, is permitted under a material transfer agreement entered into and between the NCI and CRE.

There are no known patent conflicts or freedom to operate issues at this time which could encumber our ability to commercialize the PKC ε activators for the treatment of cognition and memory disorders. However, we cannot provide any assurance that such conflicts will not arise in the future. For more information, see "Item 1A. Risk Factors—Our commercial success will depend, in part, on our ability, and the ability of our licensors, to obtain and maintain patent protection. Our licensors' failure to obtain and maintain patent protection for our products may have a material adverse effect on our business." and "—Our licensed patented technologies may infringe on other patents, which may expose us to costly litigation."

We also have the right to re-license certain patents and patent applications in certain jurisdictions that we had licensed under the CRE License but had previously elected to relinquish. In the event that we decide to re-license any of such patents and/or patent applications, then we are required to reimburse CRE for all of the attorneys' fees, translation costs, filing fees, maintenance fees, and other costs and expenses related to such patents and/or patent applications that have been incurred since we elected to relinquish them under the CRE License.

Additional Intellectual Property

In addition, we have filed, and own, multiple patent families directed to methods of treatment and formulations with PKC activators, including bryostatin. We are, or will be, seeking patent protection for these inventions in numerous countries and regions including, among others, Europe, Canada, China and Japan.

While we seek broad coverage under our existing patent applications, there is always a risk that an alteration to the product or process may provide sufficient basis for a competitor to avoid infringement claims. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued and courts can reinterpret patent scope after issuance. Moreover, many jurisdictions including the United States permit third parties to challenge issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. Moreover, we cannot provide any assurances that any patents will be issued from our pending or any future applications or that any potentially issued patents will adequately protect our intellectual property.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, utility patents issued for applications filed in the United States are granted a term of 20 years from the earliest effective filing date of a non-provisional patent application. In

addition, in certain instances, a patent term can be extended to recapture a portion of the U.S. Patent and Trademark Office ("USPTO"), delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. The actual protection afforded by a patent may vary on a product by product basis, by country and can depend upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, and the availability of legal remedies in a particular country and the validity and enforceability of the patent.

We also rely on trademarks, trade secrets, copyright protection, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position. For example, we rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements or invention assignment agreements with our employees, contract research organizations, consultants, and any potential commercial partners. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed.

Governmental Regulation and Product Approval

The manufacturing and marketing of our potential products and our ongoing research and development activities are subject to extensive regulation by the FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries.

United States Regulation of Drugs

In the United States, the FDA approves and regulates drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA"), and implementing regulations. Before any drug product can be marketed in the United States, it must receive approval from the FDA. To receive this approval, any drug we develop must undergo rigorous preclinical testing and clinical trials that demonstrate the product candidate's safety and effectiveness for each indicated use. The FDA's extensive regulatory process controls, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, sale, and distribution of pharmaceutical products. The failure to comply with requirements under the FDCA and other applicable laws at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of enforcement letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or other governmental entities.

In general, before any new pharmaceutical product can be marketed in the United States, the process typically required by the FDA includes:

- nonclinical testing, which may include laboratory tests and animal studies, conducted in compliance with the FDA's good laboratory practice ("GLP") regulations;
- submission of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("IRB") representing each clinical site before each clinical trial may be initiated;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use, conducted in accordance with good clinical practices ("GCP") and other clinical research regulations;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current good manufacturing practice ("cGMP") requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;

- preparation and submission to the FDA of a new drug application ("NDA") requesting marketing for one or more proposed indications;
- potential FDA audits of the nonclinical study and clinical trial sites that generated the data in support of the NDA;
- review by an FDA advisory committee, where appropriate or if applicable;
- payment of user fees and securing FDA approval of an NDA or an NDA supplement (for subsequent indications or other modifications, including a change in location of the manufacturing facility); and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and the potential requirement to conduct post-approval studies.

Preclinical Testing

In the United States, drug candidates undergo rigorous preclinical, or nonclinical, testing until adequate evidence of safety and efficacy is established, prior to clinical testing in human subjects. These nonclinical studies generally evaluate the mechanism of action and pharmacology of the product and assess the potential safety and efficacy of the product. Tested compounds must be produced according to applicable cGMP requirements and preclinical safety tests must be conducted in compliance with FDA and international regulations regarding GLP. The Consolidated Appropriations Act for 2023, signed into law on December 29, 2022, (P.L. 117-328) amended the FDCA and the Public Health Service Act to specify that nonclinical testing for drugs and biologics may, but is not required to, include in vivo animal testing. According to the amended language, a sponsor may fulfill nonclinical testing requirements by completing various in vitro assays (e.g., cell-based assays, organ chips, or micro physiological systems), in silico studies (i.e., computer modeling), other human or nonhuman biology-based tests (e.g., bioprinting), or in vivo animal tests.

The results of the preclinical tests, together with manufacturing information and analytical data, are generally submitted to the FDA as part of an IND, which must become effective before human clinical trials may commence. The IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA issues a notice expressly authorizing the proposed trial to proceed or requests an extension or raises concerns about the conduct of the clinical trials as outlined in the application. If the FDA has any concerns, the sponsor of the IND and the FDA must resolve the concerns before clinical trials can begin. Regulatory authorities may require additional preclinical data before allowing the clinical trials to commence or proceed from one phase to another and could demand that the clinical trials be discontinued or suspended at any time if there are significant safety issues. Some long-term nonclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted.

Furthermore, an independent IRB for each medical center proposing to participate in the conduct of the clinical trial must review and approve the clinical protocol and patient informed consent form before commencement of the clinical trial at the respective medical center. An IRB must operate in compliance with FDA regulations.

Clinical Trials

Human clinical trials are typically conducted in four sequential phases, which may overlap or be combined:

- Phase 1. The drug is initially introduced into healthy human subjects or, in certain indications such as cancer, patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.
- Phase 2. The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to evaluate preliminarily the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3. The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to evaluate statistically the efficacy and safety of the product

for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

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

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health ("NIH") for public dissemination on its ClinicalTrials.gov data registry. Information related to the product, patient population, phase of investigation, study sites and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in some cases for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. NIH's Final Rule on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and both NIH and FDA have brought enforcement actions against non-compliant clinical trial sponsors.

In the Consolidated Appropriations Act for 2023, Congress amended the FDCA to require sponsors of a Phase 3 clinical trial, or other "pivotal study" of a new drug to support marketing authorization, to submit a diversity action plan for such clinical trial. The action plan must include the sponsor's diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. A sponsor must submit a diversity action plan to FDA by the time the sponsor submits the trial protocol to the agency for review. The FDA may grant a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect Phase 3 trial planning and timing, but if FDA objects to a sponsor's diversity action plan and requires the sponsor to amend the plan or take other actions, it may delay trial initiation.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. During all clinical trials, physicians will monitor patients to determine effectiveness of the drug candidate and to observe and report any adverse reactions or safety risks that may result from use of the drug candidate. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the GCP or other IRB requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Review of the NDA by FDA

The data from the clinical trials, together with preclinical data and other supporting information that establishes a drug candidate's profile, are submitted to the FDA in the form of an NDA or NDA supplement (for approval of a new indication if the product candidate is already approved for another indication). Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, and the sponsor of an approved NDA is subject to an annual program fee. These fees are adjusted, and typically increase, annually. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for drugs with orphan designation and a waiver for certain small businesses.

Under applicable laws and FDA regulations, FDA performs an administrative review on each submitted NDA within 45 to 60 days following submission. If deemed complete at the end of this preliminary review, the FDA will "file" the NDA, thereby triggering substantive review of the application. The FDA can refuse to file any NDA that it deems incomplete or not properly reviewable. In this event, the NDA must be resubmitted with the additional information requested by the agency, and the resubmitted application is also subject to preliminary review prior to filing. The FDA has established internal substantive review goals of six months from the filing date for priority NDAs (for drugs addressing serious or life threatening conditions for which there is an unmet medical need) and 10

months from the filing date for regular NDAs. The FDA, however, is not legally required to complete its review within these periods, and the review process is often significantly extended by FDA requests for additional information or clarification and a sponsor's process to respond to such inquiries.

The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections may cover all facilities associated with an NDA submission, including drug component manufacturing (e.g., active pharmaceutical ingredients) facilities, finished drug product manufacturing facilities and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities comply with cGMP requirements and are adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

Under the Pediatric Research Equity Act ("PREA") as amended, an NDA or supplement to an NDA must contain data that are adequate to assess the safety and efficacy of the product candidate for the claimed indications in all relevant pediatric populations and to support dosing and administration for each pediatric population for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The Food and Drug Administration Safety and Innovation Act, or the FDASIA, enacted in 2012, made permanent PREA to require a sponsor who is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration to submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 clinical trial. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including trial objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from pre-clinical studies, early phase clinical trials or other clinical development programs.

Data Review and Approval

Substantial financial resources are necessary to fund the research, clinical trials and related activities necessary to satisfy FDA requirements or similar requirements of state, local and foreign regulatory agencies. It normally takes many years to satisfy these various regulatory requirements, assuming they are satisfied. Information generated in this process is susceptible to varying interpretations that could delay, limit, or prevent regulatory approval at any stage of the process. Accordingly, the actual time and expense required to bring a product to market may vary substantially. We cannot assure you that we will submit applications for required authorizations to manufacture and/or market potential products or that any such application will be reviewed and approved by the appropriate regulatory authorities in a timely manner, if at all. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Success in early-stage clinical trials does not ensure success in later stage clinical trials. Even if a product candidate receives regulatory approval, the approval may be significantly limited to specific disease states, patient populations and dosages, or have conditions placed on them that restrict the commercial applications, advertising, promotion or distribution of these products.

Orphan Drug Designation and Exclusivity

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

receives FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same disease, except in very limited circumstances, for seven years. These very limited circumstances are (i) an inability to supply the drug in sufficient quantities or (ii) a situation in which a new formulation of the drug has shown superior safety or efficacy. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a designated orphan drug ultimately receives marketing approval for an indication broader than what was described in its orphan drug designation request, it may not be entitled to exclusivity under the Orphan Drug Act. Orphan drug exclusivity, however, also could block the approval of our product for seven years if a competitor obtains earlier approval of the same drug for the same indication.

Recent court cases have challenged FDA's approach to determining the scope of orphan drug exclusivity; however, at this time the agency continues to apply its long-standing interpretation of the governing regulations and has stated that it does not plan to change any orphan drug implementing regulations.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited review if the product is intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are fast track designation, breakthrough therapy designation and priority review designation.

Specifically, the FDA may designate a product for fast track review if the product is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. In addition, the FDA may withdraw the fast track designation if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

In 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act ("FDASIA") which established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner. Product candidates designated as breakthrough therapies are also eligible for accelerated approval.

Finally, the FDA may designate a product for priority review if it is a product designed to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes and evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months from the date of filing.

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

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw regulatory approval for the product. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA. As part of the Consolidated Appropriations Act for 2023, Congress provided FDA additional statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under the act's amendments to the FDCA, FDA may require the sponsor of a product granted accelerated approval to have a confirmatory trial underway prior to approval. The sponsor must also submit progress reports on a confirmatory trial every six months until the trial is complete, and such reports are published on FDA's website. The amendments also give FDA the option of using expedited procedures to withdraw product approval if the sponsor's confirmatory trial fails to verify the claimed clinical benefits of the product.

The FDA's Decision on an NDA

Based on the FDA's evaluation of an NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of an NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

An approval letter authorizes commercial marketing of the drug with the accompanying approved prescribing information for specific indications. If the FDA approves a product, it may limit the approved indications for use for the product; require that contraindications, warnings or precautions be included in the product labeling; require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval; require testing and surveillance programs to monitor the product after commercialization; or impose other conditions, including distribution restrictions or other risk management mechanisms. In addition, as a condition of approval, the FDA may require an applicant to develop a REMS. REMS use risk minimization strategies

beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals and elements to assure safe use, or ETASU. ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and use of patient registries. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of a product. Once granted, product approvals may be withdrawn if compliance with regulatory requirements and commitments is not maintained or problems are identified following initial marketing.

The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion, which include restrictions on promoting drugs for unapproved uses or patient populations (i.e., "off-label use"), and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing annual user fee requirements for any marketed products, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic prescheduled or unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, suspension of the approval, or complete withdrawal of the product from the market or product recalls;
- fines, warning letters, other enforcement-related letters, or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; or
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. In addition, the Drug Supply Chain Security Act, or DSCA, regulates the distribution and tracing of prescription drugs and prescription drug samples at the federal level, and set minimum standards for the regulation of drug distributors by the states. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period which culminated in November 2023. After an additional one-year stabilization period to give entities subject to the DSCSA additional time to finalize interoperable tracking systems and to ensure supply chain continuity, the applicable requirements under the DSCSA became fully enforceable as of November 27, 2024. From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

The Hatch-Waxman Act and Marketing Exclusivity

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute and also enacted Section 505(b)(2) of the FDCA. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing conducted for a drug product previously approved under an NDA, known as the reference listed drug, or RLD. Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug.

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

In contrast, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. A Section 505(b)(2) applicant may eliminate the need to conduct certain preclinical or clinical studies, if it can establish that reliance on studies conducted for a previously-approved product is scientifically appropriate. Unlike the ANDA pathway used by developers of bioequivalent versions of innovator drugs, which does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data, the 505(b)(2) regulatory pathway does not preclude the possibility that a follow-on applicant would need to conduct additional clinical trials or nonclinical studies; for example, they may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness. The FDA may then approve the new product for all or some of the label indications for which the RLD has been approved, or for any new indication sought by the Section 505(b)(2) applicant, as applicable.

In addition, under the Hatch-Waxman amendments, the FDA may not approve an ANDA or 505(b)(2) NDA until any applicable period of non-patent exclusivity for the RLD has expired. These market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. In cases where such exclusivity has been granted, an ANDA or 505(b)(2) NDA may not be filed with the FDA until the expiration of five years unless the

submission is accompanied by a certification of patent invalidity or non-infringement, in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides three years of data exclusivity for a NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving follow-on applications for drugs containing the original active agent. If there is no listed patent in the Orange Book, there may not be a certification of patent invalidity or non-infringement, and, thus, no ANDA or 505(b)(2) NDA may be filed before the expiration of an applicable non-patent exclusivity period. Five-year and three-year exclusivity also will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDCA. However, an applicant submitting a traditional NDA would be required to either conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension, also known as patent term restoration, under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. Patent term extension is generally available only for drug products whose active ingredient has not previously been approved by the FDA. The restoration period granted is typically one-half the time 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 the ultimate approval date. Patent term extension cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The United States PTO reviews and approves the application for any patent term extension in consultation with the FDA.

Pediatric Exclusivity and Pediatric Use

The Best Pharmaceuticals for Children Act ("BPCA") provides NDA holders a six-month period of non-patent marketing exclusivity attached to any other exclusivity listed with FDA—patent or non-patent—for a drug if certain conditions are met. Conditions for pediatric exclusivity include a determination by the FDA that information relating to the use of a new drug in the pediatric population may produce health benefits in that population; a written request by the FDA for pediatric studies; and agreement by the applicant to perform the requested studies and the submission to the FDA, completion of the studies in accordance with the written request, and the acceptance by the FDA, of the reports of the requested studies within the statutory timeframe. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. The issuance of a written request does not require the sponsor to undertake the described studies.

European Union Regulation of Drug Products

In addition to regulations in the United States, we are and will be subject, either directly or through our distribution partners, to a variety of regulations in other jurisdictions governing, among other things, clinical trials, the privacy of personal data and commercial sales and distribution of our products, if approved.

In Europe, for example, the process governing approval of medicinal products in the European Union follows essentially the same lines as in the United States and, likewise, generally involves satisfactorily completing preclinical laboratory tests in accordance with GLP, submission of a clinical trial application, or CTA, to relevant regulatory authorities, performance of adequate and well-controlled clinical trials in accordance with GCP, and submission of a marketing authorization application, or MAA, to the competent authorities.

Under the new Clinical Trials Regulation, which became effective in January 2022, a sponsor submits a CTA through a centralized application procedure where one EU member state's competent authority takes the lead in reviewing part I of the application, which contains scientific and medicinal product documentation, and the other national authorities only have limited involvement. Part II of the application, which contains the national and patient-level documentation, is assessed individually by each EU member state concerned. Any substantial changes to the trial protocol or other information submitted with the CTA must be notified to or approved by the relevant competent authorities and ethics committees. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Medicines used in clinical trials must be manufactured in accordance with good manufacturing practices. Other national and EU-wide regulatory requirements may also apply.

To obtain a marketing license for a new drug, or medicinal product in the European Union, the sponsor must obtain approval of a MAA. The way in which a medicinal product can be approved in the European Union depends on the nature of the medicinal product.

The centralized procedure results in a single MA granted by the European Commission that is valid across the European Union, as well as in Iceland, Liechtenstein, and Norway. The centralized procedure is compulsory for human drugs that are: (i) derived from biotechnology processes, such as genetic engineering, (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases, (iii) officially designated "orphan drugs" (drugs used for rare human diseases) and (iv) advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines. The centralized procedure may at the request of the applicant also be used for human drugs which do not fall within the above mentioned categories if the human drug (a) contains a new active substance which was not authorized in the European Community; or (b) the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization in the centralized procedure is in the interests of patients or animal health at the European Community level.

Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of a MAA by the European Medicines Agency, or EMA, is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Products for Human Use, or CHMP), with adoption of the actual MA by the European Commission thereafter. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest from the point of view of therapeutic innovation, defined by three cumulative criteria: the seriousness of the disease to be treated; the absence of an appropriate alternative therapeutic approach, and anticipation of exceptional high therapeutic benefit. In this circumstance, EMA ensures that the evaluation for the opinion of the CHMP is completed within 150 days and the opinion issued thereafter.

The mutual recognition procedure, or MRP, for the approval of human drugs is an alternative approach to facilitate individual national MAs within the European Union. Basically, the MRP may be applied for all human drugs for which the centralized procedure is not obligatory. The MRP is applicable to the majority of conventional medicinal products, and is based on the principle of recognition of an already existing national MA by one or more member states. In the MRP, a MA for a drug already exists in one or more member states of the European Union and subsequently MAAs are made in other European Union member states by referring to the initial MA. The member state in which the MA was first granted will then act as the reference member state. The member states where the MA is subsequently applied for act as concerned member states. After a product assessment is completed by the reference member state, copies of the report are sent to all concerned member states, together with the approved summary of product characteristics, labeling and package leaflet. The concerned member states then have 90 days to recognize the decision of the reference member state and the summary of product characteristics, labeling and package leaflet. National MAs within individual member states shall be granted within 30 days after acknowledgement of the agreement.

Should any member state refuse to recognize the MA by the reference member state, on the grounds of potential serious risk to public health, the issue will be referred to a coordination group. Within a timeframe of 60 days, member states shall, within the coordination group, make all efforts to reach a consensus. If this fails, the procedure is submitted to an EMA scientific committee for arbitration. The opinion of this EMA committee is then forwarded to the Commission, for the start of the decision-making process. As in the centralized procedure, this process entails consulting various European Commission Directorates General and the Standing Committee on Human Medicinal Products or Veterinary Medicinal Products, as appropriate.

An applicant may use the decentralized procedure to apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure.

In the European Union, only products for which marketing authorizations have been granted may be promoted. A marketing authorization is initially valid for five years and may be renewed at the end of such period on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA, or the applicable competent authority, with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission, or the applicable competent authority, decides on justified grounds relating to pharmacovigilance to proceed with one additional five-year renewal. Any marketing authorization which is not followed by the actual placing of the drug on the market in the European Union (in case of centralized procedure) or on the market in the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

In April 2023, the European Commission issued a proposal that will revise and replace the existing general pharmaceutical legislation. If adopted and implemented as currently proposed, these revisions will significantly change several aspects of drug development and approval in the European Union.

United Kingdom Regulation

From January 1, 2021, European Union law no longer directly applies in the United Kingdom. The United Kingdom has adopted existing European Union medicines regulation as standalone United Kingdom legislation with some amendments to reflect procedural and other requirements with respect to MAs and other regulatory provisions.

The Medicines and Healthcare products Regulatory Agency, or MHRA, is responsible for regulating the United Kingdom medicinal products market (Great Britain and Northern Ireland). In order to market medicines in the United Kingdom, manufacturers must hold a United Kingdom authorization. On January 1, 2021, all European Union MAs were converted to United Kingdom MAs subject to a manufacturer opt-out. The United Kingdom has introduced a separate UK-specific processes for regulatory submissions and medicinal product MA, and MHRA guidance states that the United Kingdom will have the power to take into account MAs made under the European Union decentralized and mutual recognition procedures. On January 1, 2024, the MHRA launched the International Recognition Procedure, or IRP, which provides for an expedited authorization procedure for products that have received positive marketing authorization decisions from trusted partner agencies, such as the EMA or the FDA. There are two available routes for assessment and recognition under the IRP:

- Recognition Route A – 60 days from validation of submission
    - Application must be based on a Reference Regulatory, or RR, MA within the previous two years
    - Any significant differences from the quality dossier approved by the RR requires assessment under Recognition Route B
    - Evidence of GMP compliance for manufacturing sites should be provided with submission
    - None of the Recognition Route B criteria are met
- Recognition Route B – 110 days from validation of submission with one planned clock stop (up to 60 days) at day 70 to allow applicant to respond to issues identified during review
    - Application must be based on a RR marketing authorization within the previous ten years.
    - Criteria requiring Recognition Route B include, among other things:

■ The RR granted a conditional or exceptional circumstances marketing authorization

- Additional manufacturing sites included in the application were not assessed by the RR or a manufacturing site is not GMP certified
- There are substantial changes to the manufacturing process compared to the process approved by the RR
- Certain product types (e.g., advanced therapy medicinal products, orphan medicines, over-the-counter medicines)
- A Risk Management Plan was not assessed by the RR
- The RR required one or more post-authorization safety studies for the product
- A companion diagnostic is necessary for correct use of the product

United Kingdom medicines legislation is subject to future regulatory change under the Medicines and Medical Devices Act 2021. This act sets out a new framework for the adoption of medicines regulation.

Different rules apply in Northern Ireland following implementation of the Northern Ireland Protocol, under which European Union central marketing applications continue to apply there. However, in March 2023, the United Kingdom government and the European Commission reached agreement on a regulatory framework to replace the Northern Ireland Protocol, referred to as the Windsor Framework. The Windsor Framework is effective as of January 1, 2025 and requires changes to the system that was previously in effect under the Northern Ireland Protocol, including the regulation of pharmaceutical products in the United Kingdom. Specifically, the MHRA is responsible for approving all medicines intended to be marketed in the United Kingdom (i.e., Great Britain and Northern Ireland), while the EMA is no longer involved in approving medicines intended for sale in Northern Ireland.

The Trade and Cooperation Agreement, which sets forth a framework for partnership between the European Union and the United Kingdom, became effective as of January 1, 2021. The Trade and Cooperation Agreement contains an Annex in relation to medicinal products with the objective of facilitating availability of medicines, promotion of public health and consumer protection in respect of medicinal products between the United Kingdom and the European Union. The Annex provides for mutual recognition of cGMP inspections and certificates, meaning that manufacturing facilities do not need to undergo duplicate inspections for the two markets. The Annex establishes a Working Group on Medicinal Products to deal with matters under the Trade and Cooperation Agreement, facilitate co-operation and for the carrying out of technical discussions. It is expected that further bilateral discussions will continue with respect to regulatory areas not the subject of the Trade and Cooperation Agreement, including pharmacovigilance. The Trade and Cooperation Agreement also does not include reciprocal arrangements for the recognition of batch testing certification. However, the United Kingdom has listed approved countries, including the European Economic Area countries, which will enable United Kingdom importers and wholesales to recognize certain certification and regulatory standards. The European Commission has not adopted such recognition procedures.

It is expected that the establishment of a separate United Kingdom authorization system, albeit with transitional recognition procedures in the United Kingdom, will lead to additional regulatory costs. In addition, additional regulatory costs may be incurred with respect to the lack of mutual recognition of batch testing and related regulatory measures.

Rest of World Government Regulation

For countries outside of the United States and the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the other applicable regulatory requirements.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

Other Government Regulation

Our research and development activities use biological and hazardous materials that are dangerous to human health and safety or the environment. We are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes resulting from these materials. We are also subject to regulation by the Occupational Safety and Health Administration and federal and state environmental protection agencies and to regulation under the Toxic Substances Control Act.

If our product candidates are approved in the United States, we will have to comply with various U.S. federal and state laws, rules and regulations pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws, rules and regulations. Violations of the fraud and abuse laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state healthcare programs, including Medicare and Medicaid. These laws include the following:

- The federal Anti-Kickback Statute ("AKS") (Section 1128B(b) of the Social Security Act) prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the AKS or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA or federal civil money penalties statute;

- The federal physician self-referral prohibition (Ethics in Patient Referral Act of 1989, as amended, commonly referred to as the Stark Law, Section 1877 of the Social Security Act), prohibits referrals by physicians of Medicare or Medicaid patients to providers of a broad range of designated healthcare services in which the physicians (or their immediate family members) have ownership interests or with which they have certain other financial arrangements;

- The federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payers if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

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

- The Civil Monetary Penalties Law (Section 1128A of the Social Security Act), which authorizes the United States Department of Health and Human Services to impose civil penalties administratively for various fraudulent or abusive acts, including among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program;

- The Physician Payment Sunshine Act (Section 1128G of the Social Security Act), which requires manufacturers of drugs, medical devices, biologicals and medical supplies covered by Medicare or Medicaid to report, on an annual basis, to the Department of Health and Human Services information related to payments and other transfers of value to physicians, certain non-physician advanced healthcare practitioners, and teaching hospitals or to entities or individuals at the request of, or designated on behalf of, the physicians, advanced healthcare practitioners, and teaching hospitals as well as certain ownership and investment interests held by physicians and their immediate family members; and

- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Sanctions for violating these federal laws include criminal and civil penalties that range from punitive sanctions, damage assessments, money penalties, imprisonment, denial of Medicare and Medicaid payments, or exclusion from participation in federal programs, or both. These laws also impose an affirmative duty on those receiving Medicare or Medicaid funding to ensure that they do not employ or contract with persons excluded from participation in the Medicare and other government healthcare programs. Additionally, many states have laws and regulations that contain prohibitions that are similar to, and in many cases broader than, these federal laws and once our products are marketed commercially, we will have to comply with these various state laws as well.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures.

State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. We also may be subject to, or may in the future become subject to, U.S. federal and state, and foreign laws and regulations imposing obligations on how we collect, use, disclose, store and process personal information. Our actual or perceived failure to comply with such obligations could result in liability or reputational harm and could harm our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our customer base and thereby decrease our future revenues.

Pharmaceutical Coverage, Pricing, and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of our products, when and if approved for marketing in the United States, will depend, in part, on the extent to which our products will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. In addition, these third-party payors are increasingly reducing reimbursements for medical products, drugs and services. Furthermore, the U.S. government, state legislatures and foreign governments have continued implementing cost containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Limited third-party reimbursement for our product candidates or a decision by a third-party payor not to cover our product candidates could reduce physician usage of our products once approved and have a material adverse effect on our sales, results of operations and financial condition.

In Europe and other countries outside of the United States, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed to. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. In some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product and therapeutic candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product and therapeutic candidates that obtain marketing approval. The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product and therapeutic candidates. In addition, future legislative and regulatory proposals or Executive Branch actions may materially impact the ability of the FDA and other regulatory agencies to operate as they have historically operated. We cannot be sure whether additional legislative changes will be enacted or executive orders imposed, or whether any of the FDA's regulations, guidances or interpretations will be changed, or what the impact of such changes on the agency and its scientific review staff, if any, may be. For example, the next FDA user fee reauthorization package is expected to enter stakeholder negotiations beginning in mid-2025, with any agreement sent to Congress in early 2027 for purposes of initiating the legislative process. Reauthorization of the prescription drug user fee program would need to be finalized by Congress by the end of September 2027 in order to avoid a disruption in FDA's review goals for NDAs and other activities supported by user fees assessed against industry. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

As previously mentioned, the primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare and other healthcare funding and applying new payment methodologies. In recent years, the U.S. Congress has considered reductions in Medicare reimbursement levels for medicines and biologics administered by physicians. The U.S. Centers for Medicare and Medicaid Services, or CMS, the agency that administers the Medicare and Medicaid programs, also has authority to revise reimbursement rates and to implement coverage restrictions for most drugs and biologics. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products we may market in the future. While Medicare regulations apply only to pharmaceutical benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors.

Furthermore, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, was enacted in March 2010, (collectively the "ACA") and, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; and established a Center for Medicare Innovation at the U.S. Centers for Medicare and Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Legislative and regulatory changes under the ACA remain possible, although it is unknown what form any such changes or any law would take, and how or whether it may affect the biopharmaceutical industry as a whole or our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry in the United States.

In addition, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Notably, on December 20, 2019, President Trump signed the Further Consolidated Appropriations Act for 2020 became law (P.L. 116-94) and included a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (the "CREATES Act"). The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic and

biosimilar product developers access to samples of brand products. Because generic and biosimilar product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic and biosimilar products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic or biosimilar product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Although lawsuits have been filed under the CREATES Act since its enactment, those lawsuits have settled privately; therefore, to date no federal court has reviewed or opined on the statutory language and there continues to be uncertainty regarding the scope and application of the law.

More recently, in August 2022, former President Biden signed into the law the Inflation Reduction Act of 2022, or the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. For example, a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the drug product's price increases faster than the rate of inflation. This calculation is made on a product-by-product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting in payment year 2026, CMS will negotiate drug prices annually for a select number of single-source Part D drugs. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities and entered into the first set of agreements with drug and biological product manufacturers for negotiated prices of 10 producers, which will become appliable for payment year 2026. However, the IRA's impact on the pharmaceutical industry in the United States remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are currently ongoing.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, in recent years, several states have formed prescription drug affordability boards ("PDABs"). Much like the IRA's drug price negotiation program, these PDABs have attempted to implement upper payment limits ("UPLs") on drugs sold in their respective states in both public and commercial health plans. In August 2023, Colorado's PDAB announced a list of five prescription drugs that would undergo an affordability review. The effects of these efforts remain uncertain pending the outcomes of several federal lawsuits challenging state authority to regulate prescription drug payment limits. Furthermore, in December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers ("PBMs") and other members of the healthcare and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. The Federal Trade Commission in mid-2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Significant efforts to change the PBM industry as it currently exists in the United States may affect the entire pharmaceutical supply chain and the business of other stakeholders, including biopharmaceutical developers like us. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug, which could have an adverse effect on customers for our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Scientific Advisory Board

The Company has established a Scientific Advisory Board ("SAB") comprised of experts in the fields of AD and other neurological diseases.

Scientific Advisory Board Chairperson & Members

Dr. George Perry, Ph.D. (Chairperson) served as a director of Neurotrope and Synaptogenix from December 2018 until September 2021. Dr. Perry served as dean of the College of Sciences and professor of Biology and Chemistry at The University of Texas at San Antonio. He additionally holds the position of Semmes Foundation Distinguished University Chair in Neurobiology. Dr. Perry has served as acting Chief Scientific Officer for Neurotez, Inc., a private company focused on Alzheimer's disease since 2010 and as a director of Neurotez, Inc. since 2008. Dr. Perry is recognized in the field of Alzheimer's research, where he has studied amyloidosis, oxidative stress, cytoskeleton, metal homeostasis, cell cycle reentry, and mitochondria. He currently serves as the editor for numerous journals and as founding editor-in-chief for the Journal of Alzheimer's Disease, an international multidisciplinary journal that specializes in Alzheimer's disease. He is a fellow of the American Association for the Advancement of Science, Texas Academy of Science, the Microscopy Society of America, past president of the American Association of Neuropathologists and the Southwestern and Rocky Mountain Division of the American Association for the Advancement of Science, a member of the Dana Alliance for Brain Initiatives, and a Fulbright Senior Specialist. Dr. Perry holds a B.A. in Zoology from the University of California, Santa Barbara and a Ph.D. in Marine Biology from Scripps Institution of Oceanography, University of California at San Diego. He completed his postdoctoral fellowship in the Department of Cell Biology at Baylor College of Medicine.

Dr. Paul Coleman, PhD, has spent several decades as a Full Professor at the University of Rochester School of Medicine during which time he was Director of the University of Rochester Medical Center Alzheimer's Disease Center and Director of an NIH Training Program in Neurobiology of Aging. In 2015, he moved his laboratory to the Neurodegenerative Disease Research Center at the Bio-design Institute, Arizona State University. Dr. Coleman's work has focused on differentiating changes in the brain in Alzheimer's disease from changes related to normal, non-demented ageing. Most recently, Dr. Coleman's work has expanded into the realm of epigenetics. Dr. Coleman has received a number of awards for his work, including a Leadership and Excellence in Alzheimer's Disease Award from the NIH (one of 12 ever awarded) and a Pioneer Award from the National Alzheimer's Association.

Dr. Marwan Sabbagh, MD, a leader in the field of Alzheimer's disease and related disorders, serving as the director of translational research at Cleveland Clinic Lou Ruvo Center for Brain Health. Previously Dr. Sabbagh was the Director of the Alzheimer's and Memory Disorders Division at the Barrow Neurological Institute in Phoenix, Arizona, where he was also a professor of neurology. Dr. Sabbagh has published over 320 scientific and medical research articles on Alzheimer's disease and remains a prominent investigator and key opinion leader in nationally recognized Alzheimer's prevention and treatment trials.

Professor Robert Howard, Professor and Director of the University College London Institute of Mental Health, and Chairman, Division of Psychiatry. He and his colleagues investigate ways in which psychoses in older people can be treated most effectively and safely through optimizing the use of existing antipsychotics and of novel and repurposed agents. Their trials have shown the cognitive, functional and independent living benefits of continuing dementia drugs until the late stages of Alzheimer's disease.

Dr. Zaven Katchaturian, past editor-in-chief of *Alzheimer's & Dementia*, the journal of the Alzheimer's Association. He served as an associate director for the Neuroscience & Neuropsychology of Aging Program at the National Institution on Aging, NIH. He also served as the director of the Office at Alzheimer's Disease Research, and was responsible for coordinating all Alzheimer's disease related activities NIH-wide.

Competition

We compete with many companies, research institutes, hospitals, governments and universities that are working to develop products and processes to treat AD. Many of these entities have substantially greater financial, technical, manufacturing, marketing, distribution and other resources than we do. However, there has been a limited number of new product introductions in the last 20 years for the treatment of AD symptoms in patients who begin exhibiting the memory and cognitive disorders associated with the disease. All of the products introduced to date for the treatment of AD have yielded negative or marginal results with little effect on the progression of AD and no improvement in the memory or cognitive performance of the patients receiving these therapies. We believe we are the only company currently pursuing PKC ε activation (with consequent prevention of neuronal death and induction synaptic network

growth) as a mechanism to treat AD and neurodegenerative disease. Although we believe that we have no direct competitors working in this same field at the present time, we cannot provide assurance that our competitors will not discover compounds or processes that may be competitive with our products and introduce such products or processes before us.

Employees and Human Capital Resources

As of the date of this Annual Report on Form 10-K, we have four full-time personnel, including three executive officers and one employee who is primarily engaged in administrative activities. We also have two part-time research and development and regulatory consultants. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We believe that relations with our employees and consultants are good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purpose of our 2020 Equity Incentive Plan is to attract, retain and reward personnel through the granting of stock-based compensation awards, in order to increase the stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Facilities

Our corporate headquarters and facilities are located in New York, New York. We currently lease a total of approximately 300 square feet of building space in New York dedicated to company administration. The lease on our existing New York expires on June 30, 2025, and has a rent and other related expenses of approximately $5,900 per month.

Legal Proceedings

There are no legal proceedings against the Company and the Company is unaware of any such proceedings contemplated against it.

Corporate Information

We were incorporated in the State of Delaware on October 31, 2012 as “Neurotrope Bioscience, Inc.,” and on August 23, 2013 we were acquired by Neurotrope, Inc. (“Neurotrope”) as a wholly owned subsidiary. On December 7, 2020, Neurotrope completed the complete legal and structural separation of Synaptogenix, Inc. from Neurotrope (the “Spin-Off”).

Our principal executive offices are located at 1185 Avenue of the Americas, 3rd Floor, New York, New York, and our telephone number is (973) 242-0005. Our website is located at www.synaptogen.com. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) will be made available free of charge on our website as soon as reasonably practicable after we electronically file these materials with, or furnish it to, the SEC on their website located at www.sec.gov. The contents of our website are not incorporated into this Annual Report on Form 10-K, and our reference to the URL for our website is intended to be an inactive textual reference only. The information contained on, or that can be accessed through, our website is not a part of this Annual Report on Form 10-K.

Item 1A. Risk Factors.

An investment in shares of our common stock is highly speculative and involves a high degree of risk. We face a variety of risks that may affect our operations and financial results and many of those risks are driven by factors that we cannot control or predict. Before investing in our common stock you should carefully consider the following risks, together with the financial and other information contained in this report. If any of the following risks actually occurs, our business, prospects, financial condition and results of operations could be materially adversely affected. In that case, the trading price of our common stock would likely decline and you may lose all or a part of your investment. Only those investors who can bear the risk of loss of their entire investment should invest in our common stock.

Risk Factor Summary

We are providing the following summary of the risk factors contained in this Annual Report on Form 10-K to enhance the readability and accessibility of our risk factor disclosures. We encourage you to carefully review the full risk factors contained in this Annual Report on Form 10-K in their entirety for additional information regarding the material.

- Our exploration and pursuit of strategic alternatives may not be successful.
- In the event that we do not successfully identify a viable strategic option or, consummate such a transaction, or if we are unable to raise sufficient capital to fund our operations and commercialize Bryostatin-1, our board of directors may determine that a liquidation and dissolution of our business approved by stockholders is the best method to seek to maximize stockholder value. In such an event, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.
- If we continue to execute our current development strategy, we will need additional financing to fund our operations in the future. If we are unable to obtain additional financing on acceptable terms, we will need to curtail or cease our development plans and operations.
- Our ongoing viability as a company depends on our ability to successfully develop and commercialize our licensed technology. If the CRE License were terminated, we may be required to cease operations.
- We rely on independent third-party contract research organizations to perform clinical and non-clinical studies of our drug candidate and to perform other research and development services.
- We have relied on the representations and materials provided by CRE, including scientific, peer-reviewed and non-peer reviewed publications, abstracts, slides, internal documents, verbal communications, patents and related patent filings, with respect to the results of its research related to our proposed products.
- We have a limited operating history upon which investors can evaluate our future prospects.
- The commencement and completion of clinical trials can be delayed or prevented for a number of reasons, including, but not limited to, reasons related to the business, the economy and industry and government regulations.
- Data from our Bryostatin-1 Phase 2 clinical trial, from our confirmatory Phase 2 clinical trial and our expanded Phase 2 clinical trial may be subject to differing interpretations, and regulatory agencies, medical and scientific experts and others may not share the Company’s views of the data.
- We have not generated any revenues since our inception and we do not expect to generate revenue for the foreseeable future. If we do not generate revenues and achieve and sustain profitability, we will likely need to curtail or cease our development plans and operations.
- We are dependent on Dr. Alan Tuchman, M.D., our Chief Executive Officer, for the successful execution of our business plan. The loss of Dr. Tuchman or other key members of our management team could have a material adverse effect on our business prospects.
- We may not be able to protect our trade secrets and other unpatented proprietary technologies, which could give our competitors an advantage over us.
- We are partly dependent upon the NCI to supply bryostatin for our clinical trials.
- We expect to rely on third parties to manufacture our proposed products and, as a result, we may not be able to control our product development or commercialization.

- We may rely on third parties for marketing and sales and our revenue prospects may depend on their efforts.
- If our products are not accepted by patients, the medical community or health insurance companies, our business prospects will suffer.
- The branded prescription segment of the pharmaceutical industry in which we operate is competitive, and we are particularly subject to the risks of such competition.
- A successful liability claim, such as a clinical trial liability claim, against us could have a material adverse effect on our financial condition even with such insurance coverage.
- Disruptions in federal government operations or extended government shutdowns may negatively impact our business.
- Our business and operations would suffer in the event of computer system failures.
- We are currently operating in a period of economic uncertainty and capital markets disruption.
- Failure to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could materially and adversely affect us.
- In connection with our separation from Neurotrope, we have agreed to indemnify Neurotrope for certain liabilities which could negatively impact our financial positions.
- We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.
- If our shares of Common Stock become subject to the penny stock rules, it would become more difficult to trade our shares.
- A significant number of our shares of Common Stock are or will be eligible for future sale, which may cause the market price for our Common Stock to decline.
- We do not expect to pay any cash dividends for the foreseeable future.
- Provisions in our certificate of incorporation, our bylaws or Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our Common Stock.
- We have identified material weaknesses in our internal control over financial reporting, which could negatively impact on our ability to report our results of operations and financial condition accurately and in a timely manner.
- You may experience dilution of your ownership interests because of the future issuance of additional shares of our Common Stock. Further, we may obtain additional capital through the issuance of preferred stock, which may limit your rights as a holder of our Common Stock.
- We are an “emerging growth company,” and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

Risks Related to Our Evaluation of Strategic Alternatives

Our exploration and pursuit of strategic alternatives may not be successful.

In December 2024, our board of directors formed an independent special committee (the "Special Committee") to explore strategic opportunities to create and enhance value for investors, including promising drug development platforms and/or compelling new technologies and services with the goal of maximizing stakeholder value.

Despite our plan to devote significant efforts to identify and evaluate potential strategic options, the process may not result in any definitive offer to consummate such a transaction, or, if we receive such a definitive offer, the terms may not be as favorable as anticipated or may not result in the execution or approval of a definitive agreement. Even if we enter into a definitive agreement, we may not be successful in completing a transaction or, if we complete such a transaction, it may not enhance stockholder value or deliver expected benefits. Since we may not ultimately pursue or consummate a strategic transaction, we have begun to evaluate other options for maximizing the value of Bryostatin-1, which may include seeking to raise capital to support the commercialization of Bryostatin-1.

In the event that we do not successfully identify a viable strategic option or, consummate such a transaction, or if we are unable to raise sufficient capital to fund our operations and commercialize Bryostatin-1, our board of directors may determine that a liquidation and dissolution of our business approved by stockholders is the best method to seek to maximize stockholder value.

In the event that we do not successfully identify a viable strategic option or, consummate such a transaction, or if we are unable to raise sufficient capital to fund our operations and commercialize Bryostatin-1, our board of directors may determine that a liquidation and dissolution of our business approved by stockholders is the best method to seek to maximize stockholder value. In such an event, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that the process to identify a strategic alternative for our business will result in a successfully consummated transaction. If we are unable to identify a viable strategic option or if such a transaction is not completed in a timely manner, or if we are unable to raise sufficient capital to fund our operations and commercialize Bryostatin-1, our board of directors may determine that a liquidation and dissolution of our business approved by stockholders is the best method to seek to maximize stakeholder value. In such an event, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations while we evaluate our strategic options.

In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of our business, we would be required to pay our outstanding obligations, as well as to make reasonable provisions for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the satisfaction of such obligations. In addition, we may be subject to litigation or other claims related to a liquidation and dissolution of our business. If a liquidation and dissolution are pursued, our board of directors, in consultation with its legal and financial advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve.

Accordingly, holders of our common stock and other securities could lose all or a significant portion of their investment in the event of a liquidation and dissolution of the Company.

Risks Related to Our Business and Financial Condition

If we continue to execute our current development strategy, we will need additional financing to fund our operations in the future. If we are unable to obtain additional financing on acceptable terms, we will need to curtail or cease our development plans and operations.

As of December 31, 2024, we had approximately $17.7 million of available cash and cash equivalents. Our cash position is expected to be sufficient for at least the next 12 months, including the remaining costs of our ongoing Phase 2 clinical trial and other current development projects, from the date hereof as we continue to determine how to proceed with the current development programs. While we anticipate our current cash resources on hand will be sufficient to sustain operations and to fund our current, follow-on clinical

trial, we do not have sufficient capital to complete such planned follow-on or all necessary clinical trials in order to have a product approvable for commercial sale. As a result, we will need to raise additional capital and/or obtain a strategic partner to facilitate our development program and bringing a product to market.

Our operating plans and capital requirements are subject to change based on how we determine to proceed with respect to our current development programs for Bryostatin-1. We are currently reviewing our operating plans, and we will require additional capital in the future. Additional funds may be raised through the issuance of equity securities and/or debt financing, there being no assurance that any type of financing on terms acceptable to us will be available or otherwise occur. Debt financing must be repaid regardless of whether we generate revenues or cash flows from operations and may be secured by substantially all of our assets. Any equity financing or debt financing that requires the issuance of warrants or other equity securities to the lender would cause the percentage ownership by our current stockholders to be diluted, which dilution may be substantial. Also, any additional equity securities issued may have rights, preferences or privileges senior to those of existing stockholders. If such financing is not available when required or is not available on acceptable terms, we may be required to reduce or eliminate certain product candidates and development activities, including those related to bryostatin, the "bryologs" or PUFAs, and it may ultimately require us to suspend or cease operations, which could cause investors to lose the entire amount of their investment.

Our ongoing viability as a company depends on our ability to successfully develop and commercialize our licensed technology.

We are principally focused on developing a drug, Bryostatin-1, for the treatment of AD and other diseases, which is still in the clinical testing stage and has not yet been fully developed. Our potential success is highly uncertain since Bryostatin-1 did not achieve statistical significance on the primary endpoint, in its Phase 2 of development. On December 16, 2022, we announced that an extended confirmatory Phase 2 study of Bryostatin-1 in moderate to severe AD (Study #204) did not achieve statistical significance on the primary endpoint, which was change from baseline to week 13 in the SIB total score assessment obtained after completion of the second seven-dose course of treatment (week 28 of trial). Our other product candidates (use of Bryostatin-1 to treat Niemann Pick Type-C and Fragile X Syndrome) are earlier in their development cycles. Bryostatin-1 is also subject to regulatory approval. Our potential success depends upon our ability to raise more capital, complete development of and successfully commercialize Bryostatin-1 in a timely manner for the treatment of AD or other diseases. If we are unable to develop Bryostatin-1 for indications other than AD, the future growth of our business could be negatively impacted. We must develop Bryostatin-1, successfully test it for safety and efficacy in the targeted patient population, and manufacture the finished dosage form on a commercial scale to meet regulatory standards and receive regulatory approvals. The development and commercialization process is both time-consuming and costly, and involves a high degree of business risk. Bryostatin-1 is still at an early stage in its product development cycle, and any follow-on product candidates are still at the concept stage. The results of pre-clinical and clinical testing of our product candidates are uncertain and we cannot assure anybody that we will be able to obtain regulatory approvals of our product candidates. If obtained, regulatory approval may take longer or be more expensive than anticipated. Furthermore, even if regulatory approvals are obtained, our products may not perform as we expect and we may not be able to successfully and profitably produce and market any products. Delays in any part of the process or our inability to obtain regulatory approval of our products could adversely affect our future operating results by restricting (or even prohibiting) the introduction and sale of our products.

If the CRE License were terminated, we may be required to cease operations.

Our rights to develop, commercialize and sell certain of our proposed products, including Bryostatin-1, is, in part, dependent upon the CRE License. CRE has the right to terminate this agreement after 30 days prior notice in certain circumstances, including if we were to materially breach any provisions of the agreement after a 60-day cure period for breaches that are capable of being cured, in the event of certain bankruptcy or insolvency proceedings. Additionally, the CRE License provides that the license may not be assigned, including by means of a change of control of the Company, or sublicensed without the consent of CRE. If the CRE License were terminated, we would lose rights to a substantial portion of the intellectual property currently being developed by us and no longer have the rights to develop, commercialize and sell some of our proposed products. As a result, we may be required to cease operations under such circumstance.

We rely on independent third-party contract research organizations to perform clinical and non-clinical studies of our drug candidate and to perform other research and development services.

The CRE License requires us to use CRE to provide research and development services and other scientific assistance and support services, including clinical trials, under certain conditions. The CRE License limits our ability to make certain decisions, including those relating to our drug candidate, without CRE's consent. Under certain conditions, we may, however, also rely on independent third-party contract research organizations ("CROs"), to perform clinical and non-clinical studies of our drug candidate. We have previously entered into services agreements with WCT relating to our clinical trials of Bryostatin-1. Many important aspects of the services that may be performed for us by CROs are out of our direct control. Nevertheless, we are responsible for ensuring that each clinical trial we sponsor is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and clinical trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional nonclinical studies or clinical trials before approving our marketing applications. If there were to be any dispute or disruption in our relationship with such CROs, including WCT, the development of our drug candidate may be delayed. Moreover, in our regulatory submissions, we would expect to rely on the quality and validity of the clinical work performed by our CROs. If any of our CROs' processes, methodologies or results were determined to be invalid or inadequate, our own clinical data and results and related regulatory approvals could be materially adversely impacted.

We have relied on the representations and materials provided by CRE, including scientific, peer-reviewed and non-peer reviewed publications, abstracts, slides, internal documents, verbal communications, patents and related patent filings, with respect to the results of its research related to our proposed products.

CRE began the development of the intellectual property that forms the basis for our proposed products in 1999. We have relied on the quality and validity of the research results obtained by CRE with respect to this intellectual property, and we have conducted limited verification of the raw preclinical and clinical data produced by CRE. No independent third-party has verified any such data. If any of CRE's basic processes, methodologies or results were determined to be invalid or inadequate, our own clinical data and results and related regulatory approvals, could be materially adversely impacted.

We have a limited operating history upon which investors can evaluate our future prospects.

Our drug product candidate, Bryostatin-1, is in an early development stage and we are subject to all of the risks inherent in the establishment of a new business enterprise. While development of our product candidates was started in 1999 by CRE, we were incorporated on October 31, 2012 and on that same date entered into the Technology License and Services Agreement with CRE and NRV II, LLC for the continuing development and commercialization of our product candidates. Our proposed products are currently in the research and development stage and we have not generated any revenues, nor do we expect our products to generate revenues for the near term, if ever. As a result, any investment in our securities must be evaluated in light of the potential problems, delays, uncertainties and complications encountered in connection with a newly established pharmaceutical development business. The risks include, but are not limited to, the possibilities that any or all of our potential products will be found to be unsafe, ineffective or, that the products once developed, although effective, are not economical to market; that our competitors hold proprietary rights that preclude us from marketing such products; that our competitors market a superior or equivalent product; or the failure to receive necessary regulatory clearances for our proposed products. To achieve profitable operations, we must successfully develop, obtain regulatory approval for, introduce and successfully market, sell or license at a profit, product candidates that are currently in the research and development phase. We only have one product candidate in clinical development, i.e., Bryostatin-1 to treat AD. On December 16, 2022, we announced that an extended confirmatory Phase 2 study of Bryostatin-1 in moderate to severe AD (Study #204) did not achieve statistical significance on the primary endpoint, which was change from baseline to Week 13 in the SIB total score assessment obtained after completion of the second seven-dose course of treatment (week 28 of trial). We are currently evaluating the data and determining next steps with the development of Bryostatin-1 for AD as well as for other potential indications. No assurance can be given that our research and development efforts will be successful, that required regulatory approvals will be obtained, that any of our candidates will be safe and effective, that any products, if developed and introduced, will be successfully marketed, sold or licensed or achieve market acceptance or that products will be marketed at prices necessary to generate profits. Failure to successfully develop, obtain regulatory approvals

for, or introduce and market, sell or license our products would have material adverse effects on our business prospects, financial condition and results of operations.

If we do not obtain the necessary regulatory approvals in the United States and/or other countries, we will not be able to sell our drug candidates.

We cannot assure you that we will receive the approvals necessary to commercialize Bryostatin-1, or any other potential drug candidates we acquire or attempt to develop in the future. We will need approval from the FDA to commercialize our drug candidates in the United States and approvals from similar regulatory authorities in foreign jurisdictions to commercialize our drug candidates in those jurisdictions. In order to obtain FDA approval of Bryostatin-1 or any other drug candidate for the treatment of AD or any other indication, we must submit first an IND application and then an NDA to the FDA, demonstrating that the drug candidate is safe, pure and potent, and effective for its intended use. This demonstration requires significant research including completion of clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depending upon the type, complexity and novelty of the drug candidate and requires substantial resources for research, development and testing. We cannot predict whether our clinical trials will demonstrate the safety and efficacy of our drug candidates or if the results of any clinical trials will be sufficient to advance to the next phase of development or for approval from the FDA. We also cannot predict whether our research and clinical approaches will result in drugs or therapeutics that the FDA considers safe and effective for the proposed indications. The FDA has substantial discretion in the drug approval process. The approval process may be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may prevent or delay commercialization of, and our ability to derive revenues from, our drug candidates and diminish any competitive advantages that we may otherwise believe that we hold. Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our applications. We may never obtain regulatory clearance for any of our drug candidates. Failure to obtain FDA approval of our drug candidates will leave us without a saleable product and therefore without any source of revenues. In addition, the FDA may require us to conduct additional clinical testing or to perform post-marketing studies, as a condition to granting marketing approval of a drug product or permit continued marketing, if previously approved. If conditional marketing approval is obtained, the results generated after approval could result in loss of marketing approval, changes in product labeling, and/or new or increased concerns about the side effects or efficacy of a product. The FDA has significant post-market authority, including the explicit authority to require post-market studies and clinical trials, labeling changes based on new safety information and compliance with FDA-approved risk evaluation and mitigation strategies. The FDA's exercise of its authority has in some cases resulted, and in the future could result, in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements and potential restrictions on sales of approved drugs. In foreign jurisdictions, the regulatory approval processes generally include the same or similar risks as those associated with the FDA approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize our drug candidates for sale either within or outside the United States.

The commencement and completion of clinical trials can be delayed or prevented for a number of reasons.

On December 16, 2022, we issued a press release announcing that the expanded confirmatory Phase 2 study of Bryostatin-1 in moderate to severe AD did not achieve statistical significance on the primary endpoint. On March 7, 2023, we announced results of our analysis of secondary endpoints and post hoc analysis from our Phase 2 study of Bryostatin-1. In the secondary endpoint analysis, changes from baseline at Weeks 9, 20, 24, 30, and 42 in the SIB (Severe Impairment Battery) total score were not statistically significant in the total patient population, and no pre-specified secondary endpoints were met with statistical significance in the low-to-moderately severe AD patient stratum. However, nearly all pre-specified secondary endpoints in the most advanced and severe AD (MMSE: 10-14) patient population, with baseline MMSE-2 (Mini-Mental State Examination, 2nd Edition) scores of 10-14, were achieved with statistical significance ($p = <0.05$, 2-tailed). Data also showed statistical significance in exploratory secondary endpoints for the MMSE-2 10-14 stratum, and post hoc analysis was positive. On July 19, 2023, we announced the commencement of Phase 1 clinical trials of Bryostatin-1 in multiple sclerosis with the Cleveland Clinic. On December 20, 2024, we also disclosed the termination of our agreement with the Cleveland Clinic due to the slow pace of enrollment in the Phase 1 clinical trial. We are planning to present the totality of the clinical data for Bryostatin-1 upon trial completion. We are continuing to determine how to proceed with respect to our current development programs for Bryostatin-1. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Clinical trials can be delayed or prevented for a number of reasons, including:

- difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;

- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs, contract manufacturing organizations, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly;
- failure of our third-party contractors, such as CROs and contract manufacturing organizations, or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner;
- insufficient or inadequate supply or quality of a product candidate or other materials necessary to conduct our clinical trials;
- difficulties obtaining institutional review board, or IRB, or ethics committee approval to conduct a clinical trial at a prospective site;
- the FDA, EMA or other regulatory authority requiring alterations to any of our study designs, our pre-clinical strategy or our manufacturing plans;
- various challenges recruiting and enrolling subjects to participate in clinical trials, including size and nature of subject population, proximity of subjects to clinical sites, eligibility criteria for the trial, budgetary limitations, nature of trial protocol, change in the readiness of subjects to volunteer for a trial, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- difficulties in maintaining contact with subjects after treatment, which results in incomplete data;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; and
- varying interpretations of data by the FDA and foreign regulatory agencies.

In addition, Congress recently amended the FDCA to require sponsors of a Phase 3 clinical trial, or other "pivotal study" of a new drug to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must describe appropriate diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Although none of our product candidates has reached Phase 3 of clinical development, we must submit a diversity action plan to the FDA by the time we submit a Phase 3 trial, or pivotal study, protocol to the agency for review, unless we are able to obtain a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect the planning and timing of any future Phase 3 trial for our product candidates, but initiation of such trials may be delayed if the FDA objects to our proposed diversity action plans for any future Phase 3 trial for our product candidates. We may experience difficulties recruiting a diverse population of patients in attempting to fulfill the requirements of any approved diversity action plan.

Changes in regulatory requirements and guidance may also occur and we may need to significantly amend clinical trial protocols or submit new clinical trial protocols with appropriate regulatory authorities to reflect these changes. Amendments may require us to renegotiate terms with CROs or resubmit clinical trial protocols to IRBs or ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities, the IRB or ethics committee overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or us, due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities;
- unforeseen issues, including unexpected serious adverse events associated with a product candidate, or lack of effectiveness or any determination that a clinical trial presents unacceptable health risks;
- lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions; and

- upon a breach or pursuant to the terms of any agreement with, or for any other reason by, current or future collaborators that have responsibility for the clinical development of any of our product candidates.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we do not succeed in conducting and managing our preclinical development activities or clinical trials, or in obtaining regulatory approvals, we might not be able to commercialize our product candidates, or might be significantly delayed in doing so, which could have a material adverse effect on our business, prospects, financial condition and results of operations.

Even if regulatory approvals are obtained for our product candidates, we will be subject to ongoing government regulation. If we fail to comply with applicable current and future laws and government regulations, it could delay or prevent the promotion, marketing or sale of our products.

Even if marketing approval is obtained, a regulatory authority may still impose significant restrictions on a product's indications, conditions for use, distribution or marketing or impose ongoing requirements for potentially costly post-market surveillance, post-approval studies or clinical trials, all of which may result in significant expense and limit our ability to commercialize our products. Our products will also be subject to ongoing requirements governing the labeling, packaging, storage, advertising, distribution, promotion, recordkeeping and submission of safety and other post-market information, including adverse events, and any changes to the approved product, product labeling or manufacturing process. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practice, or cGMP, requirements and other regulations.

If we, our drug products or the manufacturing facilities for our drug products fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw marketing approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications;
- suspend or impose restrictions on operations, including costly new manufacturing requirements;
- seize or detain products, refuse to permit the import or export of products or request that we initiate a product recall; or
- refuse to allow us to enter into supply contracts, including government contracts.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad, and compliance with such regulation may be expensive and consume substantial financial and management resources. If we or any future marketing collaborators or contract manufacturers are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies or are not able to maintain regulatory compliance, it could delay or prevent the promotion, marketing or sale of our products, which would adversely affect our business and results of operations.

Data from our Bryostatin-1 Phase 2 clinical trial, from our confirmatory Phase 2 clinical trial and our expanded Phase 2 clinical trial may be subject to differing interpretations, and regulatory agencies, medical and scientific experts and others may not share the Company's views of the data.

On May 1, 2017, we reported topline results from our Phase 2 clinical trial of Bryostatin-1 for the treatment of moderate to severe AD. In January 2018, we reported the secondary analysis of data from the Phase 2 clinical trial. Further, on September 9, 2019, we reported topline results from our confirmatory Phase 2 clinical trial. On January 22, 2020, we reported additional analysis in connection with the confirmatory Phase 2 clinical trial. On December 16, 2022, we announced that an extended confirmatory Phase 2 study of Bryostatin-1 in moderate to severe AD (Study #204) did not achieve statistical significance on the primary endpoint, which was change from baseline to Week 13 in the SIB total score assessment obtained after completion of the second seven-dose course of treatment (week 28 of trial). On July 19, 2023, we announced the commencement of Phase 1 clinical trials of Bryostatin-1 in multiple sclerosis with the Cleveland Clinic. On December 20, 2024, we also disclosed the termination of our agreement with the Cleveland Clinic due to the slow pace of enrollment in the Phase 1 clinical trial. We are currently evaluating the data and determining next steps with the development of Bryostatin-1 for AD as well as for other potential indications. Further analyses of the Phase 2 data and confirmatory Phase 2 data may lead to different interpretations of the respective data than the analyses conducted to date and/or may identify important implications of the Phase 2 data, Phase 2 confirmatory data and Phase 2 extended confirmatory trial data, respectively, that are not currently known. Topline data are subject to audit and verification procedures that may result in the final data being materially different from the data we previously published. As a result, any topline data should be viewed with caution until the final data are available. In addition, clinical trial data are subject to differing interpretations, and regulatory agencies, medical and scientific experts and others may not share our views of the data. There can be no assurance that the clinical program for Bryostatin-1 will be successful in demonstrating safety and/or efficacy that we will not encounter problems or delays in clinical development, or that Bryostatin-1 will ever receive regulatory approval or be successfully commercialized.

We have not generated any revenues since our inception and we do not expect to generate revenue for the foreseeable future. If we do not generate revenues and achieve and sustain profitability, we will likely need to curtail or cease our development plans and operations.

Our ability to generate revenues depends upon many factors, including our ability to complete our currently planned clinical study and development of our proposed products, our ability to obtain necessary regulatory approvals for our proposed products and our ability to successfully commercialize market and sell our products. We have not generated any revenues since we began operations on October 31, 2012. We expect to incur significant operating losses over the next several years. If we do not generate revenues, do not achieve profitability and do not have other sources of financing for our business, we will likely need to curtail or cease our development plans and operations, which could cause investors to lose the entire amount of their investment.

Our commercial success will depend, in part, on our ability, and the ability of our licensors, to obtain and maintain patent protection. Our licensors' failure to obtain and maintain patent protection for our products may have a material adverse effect on our business.

Pursuant to the CRE License, we have obtained rights to certain patents owned by CRE or licensed to NRV II, LLC by CRE as of or subsequent to October 31, 2012. In the future, we may seek rights from third parties to other patents or patent applications. Our success will depend, in part, on our ability and the ability of our licensors to maintain and/or obtain and enforce patent protection for our proposed products and to preserve our trade secrets, and to operate without infringing upon the proprietary rights of third parties. Patent positions in the field of biotechnology and pharmaceuticals are generally highly uncertain and involve complex legal and scientific questions. We cannot be certain that we or our licensors were the first inventors of inventions covered by our licensed patents or that we or they were the first to file. Accordingly, the patents licensed to us may not be valid or afford us protection against competitors with similar technology. The failure to maintain and/or obtain patent protection on the technologies underlying our proposed products may have material adverse effects on our competitive position and business prospects.

Our licensed patented technologies may infringe on other patents, which may expose us to costly litigation.

It is possible that our licensed patented technologies may infringe on patents or other rights owned by others. We may have to alter our products or processes, pay additional licensing fees, pay to defend an infringement action or challenge the validity of the patents in court or cease activities altogether because of patent rights of third parties, thereby causing additional unexpected costs and delays to us. Patent litigation is costly and time consuming, and we may not have sufficient resources to pay for such litigation. Pursuant to the CRE License, CRE has the exclusive right (but not the obligation) to apply for, file, prosecute or maintain patents and patent applications

for our licensed technologies. However, in order to maintain our rights to use our licensed technologies, we must reimburse CRE for all of the attorney's fees and other costs and expenses related to any of the foregoing. For additional information regarding the CRE License, see "Item 1. Business — Intellectual Property — Technology License and Services Agreement." If the patents licensed to us are determined to infringe a patent owned by a third party and we do not obtain a license under such third-party patents, or if we are found liable for infringement or are not able to have such third-party patents declared invalid, we may be liable for significant money damages, we may encounter significant delays in bringing products to market or we may be precluded from participating in the manufacture, use or sale of products or methods of treatment requiring such licenses.

We are dependent on Dr. Alan Tuchman, M.D., our Chief Executive Officer, for the successful execution of our business plan. The loss of Dr. Tuchman or other key members of our management team could have a material adverse effect on our business prospects.

We are highly dependent on Dr. Tuchman, our Chief Executive Officer. We are dependent on Dr. Tuchman's and our directors' networks of contacts and experience to recruit key talent to the Company. We do not have key-man insurance on any of our officers. Loss of the services of Dr. Tuchman or other key members of our management team, or of our board of directors (the "Board") ability to identify and hire key talent, could have a material adverse effect on our business prospects, financial condition and results of operations.

We may not be able to protect our trade secrets and other unpatented proprietary technologies, which could give our competitors an advantage over us.

In addition to our reliance on patents and pending patents owned by CRE, we rely upon trade secrets and other unpatented proprietary technologies. We may not be able to adequately protect our rights with regard to such unpatented proprietary technologies or competitors may independently develop substantially equivalent technologies. We seek to protect trade secrets and proprietary knowledge, in part through confidentiality agreements with our employees, consultants, advisors and collaborators. Nevertheless, these agreements may not effectively prevent disclosure of our confidential information and may not provide us with an adequate remedy in the event of unauthorized disclosure of such information and, as a result, our competitors could gain a competitive advantage over us.

If we are unable to hire additional qualified personnel, our business prospects may suffer.

Our success and achievement of our business plans depend upon our ability to recruit, hire, train and retain other highly qualified technical and managerial personnel. Competition for qualified employees among pharmaceutical and biotechnology companies is intense, and the loss of any of such persons, or an inability to attract, retain and motivate any additional highly skilled employees required for the implementation of our business plans and activities could have a material adverse effect on us. Our inability to attract and retain the necessary technical and managerial personnel and consultants and scientific and/or regulatory consultants and advisors could have a material adverse effect on our business prospects, financial condition and results of operations.

We may not be able to in-license or acquire new development-stage products or technologies.

Our product commercialization strategy relies, to some extent, on our ability to in-license or acquire product formulation techniques, new chemical entities, or related know-how that has proprietary protection. If resources permit, we may also seek to acquire, by license or otherwise, other development stage products that are consistent with our product portfolio objectives and commercialization strategy. The acquisition of products requires the identification of appropriate candidates, negotiation of terms of acquisition, and financing for the acquisition and integration of the candidates into our portfolio. Failure to accomplish any of these tasks may diminish our growth rate and adversely alter our competitive position.

We are partly dependent upon the NCI to supply bryostatin for our clinical trials.

CRE has entered into a material transfer agreement with the NCI, pursuant to which the NCI has agreed to supply bryostatin required to synthesize Bryostatin-1 for our pre-clinical research and clinical trials. This agreement does not provide for a sufficient amount of bryostatin to support the completion of our clinical trials that we are required to conduct in order to seek FDA approval of Bryostatin-1 for the treatment of AD. Therefore, CRE or we will have to enter into one or more subsequent agreements with the NCI for the supply of additional amounts of bryostatin. If CRE or we are unable to secure such additional agreements or if the NCI otherwise discontinues for any reason supplying us with bryostatin, then we would have to either secure another source of bryostatin or discontinue our efforts to develop and commercialize Bryostatin-1 for the treatment of AD. In the interest of mitigating this risk, we have entered

into license agreements with Stanford for the development of bryostatin structural derivatives known as "bryologs" and an accelerated synthesis of Bryostatin-1 as alternative potential sources of bryostatin. In addition, we entered into the Supply Agreement with BryoLogyx on June 9, 2020, pursuant to which BryoLogyx agreed to serve as our exclusive supplier of synthetic bryostatin. There can be no assurance that we will be able to secure future bryostatin supplies from any source on commercially reasonable terms, if at all.

We expect to rely on third parties to manufacture our proposed products and, as a result, we may not be able to control our product development or commercialization.

We currently do not have an FDA approved manufacturing facility. We expect to rely on contract manufacturers to produce quantities of products and substances necessary for product commercialization. See also the risk factor above captioned "We are partly dependent upon the NCI to supply bryostatin for our clinical trials." Contract manufacturers that we use must adhere to cGMP enforced by the FDA through its facilities inspection program. If the facilities of such manufacturers cannot pass a pre-approval plant inspection, the FDA pre-market approval of our products will not be granted. As a result:

- there are a limited number of manufacturers that could produce the products for us and we may not be able to identify and enter into acceptable agreements with any manufacturers;
- the products may not be produced at costs or in quantities necessary to make them commercially viable;
- the quality of the products may not be acceptable to us and/or regulatory authorities;
- our manufacturing partners may go out of business or file for bankruptcy;
- our manufacturing partners may decide not to manufacture our products for us;
- our manufacturing partners could fail to manufacture to our specifications;
- there could be delays in the delivery of quantities needed;
- we could be unable to fulfill our commercial needs in the event we obtain regulatory approvals and there is strong market demand; or
- ongoing inspections by the FDA or other regulatory authorities may result in suspensions, seizures, recalls, fines, injunctions, revocations and/or criminal prosecutions.

If we are unable to engage contract manufacturers or suppliers to manufacture or package our products, or if we are unable to contract for a sufficient supply of required products and substances on acceptable terms, or if we encounter delays or difficulties in our relationships with these manufacturers, or with a regulatory agency, then the submission of products for regulatory approval and subsequent sales of such products would be delayed. Any such delay may have a material adverse effect on our business prospects, financial condition and results of operations.

We may rely on third parties for marketing and sales and our revenue prospects may depend on their efforts.

We currently have no experience in sales, marketing or distribution. We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our proposed products. As a result, if our product development is successful, our future success will likely depend, in part, on our ability to enter into and maintain collaborative relationships with one or more third parties for sales, marketing or distribution, on the collaborator's strategic interest in the products we have under development and on such collaborator's ability to successfully market and sell any such products. We intend to pursue collaborative arrangements regarding the sales and marketing of our products as appropriate. However, we may not be able to establish or maintain such collaborative arrangements or, if we are able to do so, they may not have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources and time will be required to establish and develop an in-house marketing and sales force with technical expertise.

To the extent that we depend on third parties for marketing and distribution, any revenues received by us will depend upon the efforts of such third parties, which may not be successful.

If our products are not accepted by patients, the medical community or health insurance companies, our business prospects will suffer.

Commercial sales of any products we successfully develop will substantially depend upon the products' efficacy and on their acceptance by patients, the medical community, providers of comprehensive healthcare insurance, healthcare benefit plan managers, the Centers for Medicare and Medicaid Services ("CMS") (which is the U.S. federal agency which administers Medicare, Medicaid and the State Children's Health Insurance Program), and other organizations. Widespread acceptance of our products will require educating patients, the medical community and third-party payors of medical treatments as to the benefits and reliability of the products. Our proposed products may not be accepted, and, even if they are accepted, we are unable to estimate the length of time it would take to gain such acceptance.

The branded prescription segment of the pharmaceutical industry in which we operate is competitive, and we are particularly subject to the risks of such competition.

The branded prescription segment of the pharmaceutical industry in which we operate is competitive, in part because the products that are sold require extensive sales and marketing resources invested in their commercialization. The increasing cost of prescription pharmaceuticals has caused providers of comprehensive healthcare insurance, healthcare benefit plan managers, CMS, as well as other organizations, collectively known as third-party payors, to tightly control and dictate their drug formulary plans to control the costs associated with the use of prescription pharmaceutical products by enrollees in these plans. Our ability to gain formulary access to drug plans supported by these third-party payors is substantially dependent on the differentiated patient benefit that our proposed products can provide, compared closely to similar products claiming the same benefits or advantages. We may not be able to differentiate our proposed products from those of our competitors, successfully develop or introduce new products that are less costly or offer better performance than those of our competitors, or offer purchasers of our proposed products payment and other commercial terms as favorable as those offered by our competitors. We expect that some of our proposed products, even if successfully developed and commercialized, will eventually face competition from a significant number of biotechnology or large pharmaceutical companies. Because most of our competitors have substantially greater financial and other resources than we have, we are particularly subject to the risks inherent in competing with them. The effects of this competition could materially adversely affect our business prospects, financial condition and results of operations.

We compete with many companies, research institutes, hospitals, governments and universities that are working to develop products and processes to treat or diagnose AD. We believe that others are doing research on Fragile X syndrome and Niemann Pick disease. Many of these entities have substantially greater financial, technical, manufacturing, marketing, distribution and other resources than we do. However, there has been a limited number of new product introductions in the last 20 years for the treatment of AD symptoms in patients who begin exhibiting the memory and cognitive disorders associated with the disease. All of the products introduced to date for the treatment of AD have yielded negative or marginal results with little effect on the progression of AD and no improvement in the memory or cognitive performance of the patients receiving these therapies. The absolute determination of AD in patients is currently achieved only upon autopsy. We believe we are the only company currently pursuing PKC ε activation as a mechanism to treat AD and neurodegenerative diseases. Although we believe that we have no direct competitors working in this same field on product candidates using the same mechanism of action, we cannot provide assurance that our competitors will not discover compounds or processes that may be competitive with our products and introduce such products or processes before us.

We are developing our product candidates to address unmet medical needs in the treatment of AD and other neurodegenerative diseases. Our competition will be determined in part by the potential indications for which drugs are developed and ultimately approved by regulatory authorities. Additionally, the timing of market introduction of some of our potential products or of competitors' products may be an important competitive factor. Accordingly, the relative speed with which we can develop our product candidates, complete preclinical testing, clinical trials and approval processes and supply commercial quantities to market are expected to be important competitive factors. We expect that competition among products approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent position.

Our business will expose us to potential product liability risks, which could result in significant product liability exposure.

Our business will expose us to potential product liability risks that are inherent in the testing, designing, manufacturing and marketing of human therapeutic products. Product liability insurance in the pharmaceutical industry is generally expensive, and we may not be able to obtain or maintain product liability insurance in the future on acceptable terms or with adequate coverage against potential liabilities, if at all. A successful products liability claim brought against us could have a material adverse effect on our business prospects, financial condition and results of operations.

A successful clinical trial liability claim against us could have a material adverse effect on our financial condition even with such insurance coverage.

Our business will expose us to potential liability that results from risks associated with conducting clinical trials of our product candidates. Although we have procured clinical trial product liability insurance coverage for our Bryostatin-1 product candidate with coverages and deductibles we believe are adequate, there is no guarantee that our coverage will be adequate to satisfy any liability we may incur. We do not currently have insurance with respect to any other drug product. A successful clinical trial liability claim brought against us could have a material adverse effect on our business prospects, financial condition and results of operations even if we successfully obtain clinical trial insurance.

A successful liability claim against us could have a material adverse effect on our financial condition.

Our business and actions can expose us to potential liability risks that are inherent in business, generally, and in the pharmaceutical industry, specifically. While we maintain commercial general liability insurance with coverages and deductibles we believe are adequate, there is no guarantee that our coverage will be adequate to satisfy any liability we may incur. A successful liability claim brought against us could have a material adverse effect on our business prospects, financial condition and results of operations.

Reforms in the healthcare industry and the uncertainty associated with pharmaceutical and laboratory test pricing, reimbursement and related matters could adversely affect the marketing, pricing and demand for our products.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable U.S. federal and state laws and agency regulation, as well as foreign laws and regulations, could have a materially negative impact on our business. In the United States and in some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval of our product candidates or any of our potential future product candidates, restrict or regulate post-approval activities, or affect our ability to profitably sell any product candidates for which we obtain marketing approval. Increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. We cannot be sure whether additional legislative changes will be enacted, or whether any of the FDA's regulations, guidances or interpretations will be changed, or what the impact of such changes on the agency and its scientific review staff, if any, may be.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which reimbursement for these product candidates and related treatments will be available from governmental authorities or health care programs, private health plans, and other organizations. Even if we succeed in bringing one or more products to the market, such products may not be considered medically necessary or cost-effective, and the amount reimbursed for the products may be insufficient to allow us to sell them on a competitive basis. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in health care systems with the stated goals of containing health care costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a focus of these efforts and has been significantly affected by major legislative initiatives. For examples, see the section above titled "Governmental Regulation and Product Approval – Healthcare Reform."

Increasingly, third-party payors are challenging the prices charged for medical products and requiring that pharmaceutical companies provide them with predetermined discounts from list prices. Novel medical products, if covered at all, may be subject to enhanced utilization management controls designed to ensure that the products are used only when medically necessary. Such utilization management controls may discourage the prescription or use of a medical product by increasing the administrative burden associated with its prescription or creating coverage uncertainties for prescribers and patients. We cannot be sure that reimbursement will be available for any product candidate we may be able to commercialize and, if reimbursement is available, that the level of reimbursement

will be adequate. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

We cannot predict the nature of any measures that may be adopted by governmental authorities or private payors or their effect on our competitive position. Our ability to market our products depends, in part, on reimbursement levels for them and related treatment established by healthcare providers, private health insurers and other organizations, including health maintenance organizations and managed care organizations. In the event that governmental authorities enact additional legislation or adopt regulations that affect third party coverage and reimbursement, demand for our products may be reduced, which may materially adversely affect our business prospects, financial condition and results of operations.

Disruptions in federal government operations or extended government shutdowns may negatively impact our business.

Any disruption in federal government operations could have a material adverse effect on our business, results of operations and financial condition. An extended federal government shutdown resulting from failure to pass budget appropriations, to adopt continuing funding resolutions or to raise the debt ceiling, for example, or any other budgetary decisions limiting or delaying federal government spending, could negatively impact our business. In particular, disruptions in federal government operations may negatively impact regulatory approvals and guidance that are important to our operations, and create uncertainty about the pace of upcoming healthcare regulatory developments.

Our business and operations would suffer in the event of computer system failures.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. Like other companies, we may from time to time experience threats to our data and systems, including malware and computer virus attacks, unauthorized access, systems failures and disruptions. See "We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure" below for more information regarding risks related to possible cyberattacks.

If a disruption event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of Bryostatin-1 could be delayed.

Consolidation in the pharmaceutical industry could materially affect our ability to operate as an independent entity.

The pressure to grow revenues while containing the escalating costs of basic research and development has resulted in an increase in mergers and acquisitions in our industry. More consolidation in the pharmaceutical industry is expected over the next five years. We could become an acquisition target by a larger competitor and, as a consequence, suffer serious disruptions to our business model or even lose control of our ability to operate as an independent entity. Such events could have a material adverse effect on our product development efforts or the commercialization of our proposed products.

We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability due to the military conflict between Russia and Ukraine and armed conflicts between Israel and Hamas. Our business, financial condition and results of operations may be materially and adversely affected by any negative impact on the global economy and capital markets resulting from the conflicts in Ukraine, the Gaza Strip or any other geopolitical tensions.

U.S. and global markets have experienced volatility and disruption following the escalation of geopolitical tensions, including the military conflict between Russia and Ukraine, armed conflicts between Israel and Hamas and the related Red Sea crisis, where Houthi forces based in Yemen have been attacking freighters. Although the length and impact of the ongoing conflicts is highly unpredictable, such conflicts could lead to market disruptions, including significant volatility in commodity prices, credit and capital markets, as well as supply chain interruptions. We are continuing to monitor the situations in Ukraine, the Gaza Strip and globally and

assessing their potential impacts on our business. In addition, sanctions on Russia and hostilities involving Israel could adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds.

Any of the above-mentioned factors could affect our business, prospects, financial condition, and operating results. The extent and duration of the military actions, sanctions and resulting market disruptions are impossible to predict, but could be substantial.

Failure to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could materially and adversely affect us.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the Dodd-Frank Act and are required to prepare our financial statements according to the rules and regulations required by the SEC. In addition, the Exchange Act requires that we file annual, quarterly and current reports. Our failure to prepare and disclose this information in a timely manner or to otherwise comply with applicable law could subject us to penalties under federal securities laws, expose us to lawsuits and restrict our ability to access financing. In addition, the Sarbanes-Oxley Act requires that, among other things, that we establish and maintain effective internal controls and procedures for financial reporting and disclosure purposes. Internal control over financial reporting is complex and may be revised over time to adapt to changes in our business, or changes in applicable accounting rules. We cannot assure you that our internal control over financial reporting will be effective in the future or that a material weakness will not be discovered with respect to a prior period for which we had previously believed that internal controls were effective.

We have identified material weaknesses in our internal control over financial reporting. Matters affecting our internal controls may cause us to be unable to report our financial information on a timely basis or may cause us to restate previously issued financial information, and thereby subject us to adverse regulatory consequences, including sanctions or investigations by the SEC, or violations of applicable stock exchange listing rules. There could also be a negative reaction in the financial markets due to a loss of investor confidence in our company and the reliability of our financial statements. Confidence in the reliability of our financial statements is also likely to suffer if we or our independent registered public accounting firm reports a material weakness in our internal control over financial reporting. This could have a material and adverse effect on us by, for example, leading to a decline in our share price and impairing our ability to raise additional capital. Further, there are inherent limitations to the effectiveness of any system of controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. We could face additional litigation exposure and a greater likelihood of an SEC enforcement or other regulatory action if further restatements were to occur or other accounting-related problems emerge.

We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (e.g., state breach notification laws), federal (e.g., HIPAA, as amended by HITECH), and international law (e.g., the GDPR) and may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business.

In addition, the computer systems of various third parties on which we rely, and other contractors, consultants and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyber-attacks and any such attacks could result in losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

Our failure to comply with data protection laws and regulations could lead to government enforcement actions, private litigation and/or adverse publicity and could negatively affect our operating results and business.

We are subject to data protection laws and regulations that address privacy and data security. The legislative and regulatory landscape for data protection continues to evolve, and there has been an increasing focus on privacy and data security issues with the potential to affect our business. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal consumer protection laws govern the collection, use, disclosure and protection of health-related and other personal data. Many U.S. states are also enacting consumer privacy statutes to enhance protections for personal data and to provide residents with more choices concerning their data collected by businesses, increasing compliance complexity and increasing risks of failures to comply.

In addition, foreign data protection, privacy, and other laws and regulations can be more restrictive than those in the United States. Data localization laws in some countries generally mandate that certain types of data collected in a particular country be stored and/or processed within that country. We could be subject to audits in Europe and around the world, particularly in the areas of consumer and data protection, as we operate our business. Legislators and regulators may make legal and regulatory changes, or interpret and apply existing laws, in ways that require us to incur substantial costs, expose us to unanticipated civil or criminal liability, or cause us to change our business practices. These changes or increased costs could negatively impact our business and results of operations in material ways. For example, the General Data Protection Regulation ("GDPR") imposes requirements in the European Economic Area relating to, among other things, consent to process personal data of individuals, the information provided to individuals regarding the processing of their personal data, the security and confidentiality of personal data, notifications in the event of data breaches and use of third-party processors. GDPR also imposes restrictions on the transfer of personal data from the EEA to third countries like the United States.

Applicable data privacy and data protection laws may conflict with each other, and by complying with the laws or regulations of one jurisdiction, we cannot be assured of compliance with the laws or regulations of another jurisdiction. Despite our efforts, we may not have fully complied in the past and may not in the future. Furthermore, the number of government investigations related to data security incidents and privacy violations continues to increase and government investigations typically require significant resources and generate negative publicity, which could harm our business and reputation. Failure to comply with data protection laws may expose us to risk of enforcement actions taken by data protection authorities or other regulatory agencies, private rights of action in some jurisdictions, potential significant fines and penalties if we are found to be non-compliant, and/or adverse publicity, any of which could negatively affect our operating results and business.

Our employees, independent contractors, principal investigators, contract research organizations, consultants or vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, contract research organizations, consultants or vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA; manufacturing standards; federal and state healthcare fraud and abuse laws and regulations; or laws that require the true, complete and accurate reporting of financial information or data. In addition, sales,

marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials or creating fraudulent data in our nonclinical studies or clinical trials, which could result in regulatory sanctions and serious harm to our reputation.

It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished potential profits and future earnings, and curtailment of our operations, any of which could adversely affect our business, financial condition, results of operations or prospects.

Risks Relating to our Common Stock and the Securities Market

The market price of our common stock has been volatile.

The market price of our Common Stock has fluctuated substantially due to a number of factors, many of which are beyond our control and may not be related to our operating performance. These fluctuations could cause you to lose all or part of your investment in our Common Stock since you might be unable to sell your shares at or above the price you paid. Factors that could cause fluctuations in the trading price of our common stock include the following:

- price and volume fluctuations in the overall stock market from time to time;
- volatility in the trading prices and trading volumes of stocks in our industry;
- changes in operating performance and stock market valuations of other companies generally, or those in our industry in particular;
- sales of shares of our Common Stock by us or our stockholders;
- failure of securities analysts to maintain coverage of us, changes in financial estimates by securities analysts who follow our company or our failure to meet these estimates or the expectations of investors;
- the financial projections we may provide to the public, any changes in those projections or our failure to meet those projections;
- announcements by us or our competitors of new offerings or features;
- the public's reaction to our press releases, other public announcements and filings with the SEC;
- rumors and market speculation involving us or other companies in our industry;
- actual or anticipated changes in our results of operations or fluctuations in our results of operations;
- actual or anticipated developments in our business, our competitors' businesses or the competitive landscape generally;
- litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors;
- developments or disputes concerning our intellectual property or other proprietary rights;

- announced or completed acquisitions of businesses, services or technologies by us or our competitors;
- new laws or regulations or new interpretations of existing laws or regulations applicable to our business;
- changes in accounting standards, policies, guidelines, interpretations or principles;
- any significant change in our management; and
- general economic conditions and slow or negative growth of our markets.

In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

If we fail to meet the continued listing standards of Nasdaq, our common stock may be delisted, which may adversely affect the market price and liquidity of our common stock.

Our common stock is currently traded on the Nasdaq. Nasdaq requires us to meet certain financial, public float, bid price and liquidity standards on an ongoing basis in order to continue the listing of our common stock, including that we maintain a minimum closing bid price of $1.00 per share (the "Minimum Bid Price Requirement").

There can be no assurance that we will remain in compliance with the Minimum Bid Price Requirement or that we will be able to maintain compliance with the other requirements for continued listing of our common stock on Nasdaq. If our common stock is delisted and we are unable to list our common stock on another U.S. national securities exchange, we expect our securities would be quoted on an over-the-counter market. If this were to occur, our stockholders could face significant material adverse consequences, including limited availability of market quotations for our common stock and reduced liquidity for the trading of our securities. Furthermore, if our common stock were delisted it could adversely affect our ability to obtain financing for the continuation of our operations and/or result in the loss of confidence by investors, customers, suppliers and employees.

A significant number of our shares of Common Stock are or will be eligible for future sale, which may cause the market price for our Common Stock to decline.

As of December 31, 2024, we had an aggregate of 1,357,165 shares of Common Stock outstanding. Except for 7,681 shares, all of those shares are freely tradable without restriction or registration under the Securities Act of 1933, as amended (the "Securities Act").

On September 10, 2024, we entered into a Securities Purchase Agreement (the "Series C Purchase Agreement") with certain accredited investors (the "Series C Investors"), pursuant to which we agreed to sell to the Series C Investors (i) in a registered direct offering, an aggregate of 1,793 shares of the Company's newly-designated Series C convertible preferred stock, par value $0.0001, with a stated value of $1,000 per share (the "Series C Preferred Stock"), initially convertible into up to 448,250 shares of Common Stock (the "Registered Conversion Shares") and (ii) in a concurrent private placement, an aggregate of 3,207 shares of the Series C Preferred Stock, initially convertible into up to 801,750 shares of Common Stock (the "Unregistered Conversion Shares" and, together with the Registered Conversion Shares, the "Series C Conversion Shares") at an initial conversion price of $4.00 per share, as well as warrants (the "Series C Warrants") to acquire up to an aggregate of 1,250,000 shares of Common Stock (the "Series B Warrant Shares") (the registered direct offering and the concurrent private placement collectively, the "Series C Offering"). In connection with the Series C Purchase Agreement, on September 10, 2024, we and the Series C Investors entered into a Registration Rights Agreement (the "Series C Registration Rights Agreement"), pursuant to which we were required to file a resale registration statement with the SEC to register for resale 200% of the Unregistered Conversion Shares and 200% of the Series C Warrant Shares. We filed a registration statement for the resale of such securities on October 10, 2024, which was declared effective by the SEC on October 21, 2024.

We are unable to predict whether large amounts of our Common Stock will be sold in the open market. We are also unable to predict whether a sufficient number of buyers of our Common Stock to meet the demand to sell shares of our Common Stock at attractive prices would exist at that time. It is possible that our stockholders will sell the shares of our Common Stock for various reasons. For

example, such stockholders may not believe that our business profile or our level of market capitalization as an independent company fit their investment objectives. The sale of significant amounts of our Common Stock or the perception in the market that this will occur may lower the market price of our Common Stock.

If securities or industry analysts do not publish research or publish misleading or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our Common Stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not currently have and may never obtain research coverage for our Common Stock. If there is no research coverage of our Common Stock, the trading price for shares of our Common Stock may be negatively impacted. If we obtain research coverage for our Common Stock and if one or more of the analysts downgrades our stock or publishes misleading or unfavorable research about our business, our stock price would likely decline. If one or more analyst ceases coverage of our Common Stock or fails to publish reports on us regularly, demand for our Common Stock could decrease, which could cause our Common Stock price or trading volume to decline.

We do not expect to pay any cash dividends for the foreseeable future.

We do not expect to declare or pay any cash dividend for the foreseeable future. We expect to use future earnings, if any, to fund business growth. Therefore, stockholders will not likely receive any funds absent a sale of their shares. If we do not pay dividends, our Common Stock may be less valuable because a return on your investment will only occur if our stock price appreciates. We cannot assure stockholders of a positive return on their investment when they sell their shares, nor can we assure that stockholders will not lose the entire amount of their investment.

Provisions in our certificate of incorporation, our bylaws or Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our Common Stock.

Provisions of our articles of incorporation, bylaws, shareholder rights plan or Delaware law may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions may also prevent or frustrate attempts by our stockholders to change the composition of our Board or to replace or remove our management. These provisions include:

- limitations on the removal of directors;
- advance notice requirements for stockholder proposals and nominations;
- limitations on the ability of stockholders to call and bring business before special meetings and to take action by written consent in lieu of a meeting;
- limitations on the liability of, and the provision of indemnification to, our director and officers; and
- the ability of our Board to authorize the issuance of blank check preferred stock, which could be issued with voting, liquidation, dividend and other rights superior to our Common Stock.

In addition, we are subject to Section 203 of the DGCL, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date such person becomes an interested stockholder, unless the business combination or the transaction in which such person becomes an interested stockholder is approved in a prescribed manner. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. Generally, an "interested stockholder" is a person that, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15.0% or more of a corporation's voting stock. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by our Board and the anti-takeover effect includes discouraging attempts that might result in a premium over the market price for the shares of our Common Stock.

In addition, our amended and restated certificate of incorporation, to the fullest extent permitted by law, provides that the Court of Chancery of the State of Delaware will be the exclusive forum for any stockholder (including a beneficial owner) to bring: (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer or other employee, to us or to our stockholders, (iii) any action or proceeding asserting a claim against us or any current or former director, officer or other employee arising out of or pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our bylaws (in each case, as they may be amended from time to time), (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our bylaws (including any right, obligation, or remedy thereunder); (v) any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; or (vi) any action asserting a claim governed by the internal affairs doctrine against us or any of our directors, officers or other employees, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants. Notwithstanding the foregoing, this exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act or any other claim for which the federal district courts of the United States of America shall be the sole and exclusive forum.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our Common Stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that investors could receive a premium for their shares of our Common Stock in an acquisition.

You may experience dilution of your ownership interests because of the future issuance of additional shares of our Common Stock.

Any future issuance of our equity or equity-backed securities will dilute then-current stockholders' ownership percentages and could also result in a decrease in the fair market value of our equity securities, because our assets would be owned by a larger pool of outstanding equity. As described above, we will need additional financing to continue our operations and may raise additional capital through public or private offerings of our common or preferred stock or other securities that are convertible into or exercisable for our common or preferred stock. We may also issue such securities in connection with hiring or retaining employees and consultants (including stock options and other equity compensation issued under our equity incentive plans), as payment to providers of goods and services, in connection with future acquisitions or for other business purposes. Our Board may at any time authorize the issuance of additional common or preferred stock without common stockholder approval, subject only to the total number of authorized common and preferred shares set forth in our Articles of Incorporation. The terms of equity securities issued by us in future transactions may be more favorable to new investors, and may include dividend and/or liquidation preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect. Also, the future issuance of any such additional shares of our common or preferred stock or other securities may create downward pressure on the trading price of our Common Stock. There can be no assurance that any such future issuances will not be at a price (or exercise prices) below the price at which shares of our Common Stock are then traded.

We may obtain additional capital through the issuance of preferred stock, which may limit your rights as a holder of our Common Stock.

Without any stockholder vote or action, our Board may designate and approve for issuance shares of our preferred stock. The terms of any preferred stock may include priority claims to assets and dividends and special voting rights which could limit the rights of the holders of our Common Stock. The designation and issuance of preferred stock favorable to current management or stockholders could make any possible takeover of us or the removal of our management more difficult.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our Common Stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our Common Stock that is held by non-affiliates exceeds $700 million as of the last business day of the most recently completed second fiscal quarter. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- providing only two years of audited financial statements in addition to any required unaudited interim financial statements and a correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in our initial registration statement;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. We will continue to take advantage of these reduced reporting requirements for as long as we remain an emerging growth company. We cannot predict whether investors will find our Common Stock less attractive if we rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

We recognize the critical importance of maintaining the trust and confidence of business partners and employees toward our business and are committed to protecting the confidentiality, integrity and availability of our business operations and systems. Our Board is actively involved in oversight of our risk management activities, and cybersecurity represents an important element of our overall approach to risk management. In general, we seek to address cybersecurity risks by utilizing reputable third party vendors and service providers to manage and maintain our information systems and assets in accordance with strong cybersecurity policies, standards, processes and practices, and by preserving the confidentiality, security and availability of the information that we collect and store by identifying, preventing and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

We consider risks from cybersecurity threats alongside other company risks as part of our overall risk assessment process. We face risks related to cybersecurity such as unauthorized access, cybersecurity attacks and other security incidents, including as perpetrated by hackers and unintentional damage or disruption to hardware and software systems, loss of data, and misappropriation of confidential information. To identify and assess material risks from cybersecurity threats, we maintain policies to ensure our systems are effective and prepared for information security risks. For example, our Synaptogenix Information Security Policy, which applies to all employees, contractors and third parties granted access to our systems and provides guidelines for maintaining information security, including safeguarding personal and company-issued digital devices, learning to detect phishing and other attacks, restricting data transfer, and ensuring the judicious use of the internet and social media. We also maintain a more general Risk Management Strategy that sets forth our procedures for identifying, assessing, responding to, monitoring, and reporting risks, including any cyber-related risks.

Our approach to addressing cybersecurity threat risks also includes mitigating risk associated with our use of third-party service providers. For example, when we enter into contracts with third-party collaborators or vendors pursuant to which sensitive business or personal data will be shared or accessible, we include provisions safeguarding the protection of confidential information. We also utilize a third party service provider to maintain our information systems and assets and to employ technical safeguards that are designed to protect our information systems from cybersecurity threats.

Our incident response plan coordinates the activities we take to prepare for, detect, respond to and recover from cybersecurity incidents, which include processes to triage, assess severity for, escalate, contain, investigate and remediate the incident, as well as to comply with potentially applicable legal obligations and mitigate damage to our business and reputation. We maintain an Information Security Incident Response form that directs a detector of any incident to report such incident to our Information Security Officer, whom we contract through a third-party service provider. Following notice of any such incident, our Information Security Officer would then work with our Chief Financial Officer and our Board to establish an appropriate response plan and to determine the materiality of the incident and any disclosure obligations.

As discussed in more detail under “Cybersecurity Governance” below, our Board provides oversight of our risk management and strategy processes.

We describe whether and how risks from identified cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, under the heading “We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure,” which disclosures are incorporated by reference herein.

In the last three fiscal years, we have not experienced any material cybersecurity incidents and the expenses we have incurred from cybersecurity incidents were immaterial. This includes penalties and settlements, of which there were none.

Cybersecurity Governance; Management

Cybersecurity is part of our overall risk management processes. In general, our Board oversees risk management activities designed and implemented by our management, and considers specific risks, including, for example, risks associated with our strategic plan, business operations, and capital structure. Any cybersecurity incident that occurs would be brought to the immediate attention of the Board.

Our cybersecurity risk management and strategy processes, which are discussed in greater detail above, are led by a contracted third-party Information Security Officer. Such individual has over 25 years of experience in information technology, including over 14 years of experience in cybersecurity, and has a master’s degree in cybersecurity. Our Information Security Officer is informed about and monitors our cybersecurity risk through his participation in the cybersecurity risk management and strategy processes described above, including the operation of our incident response plan.

Item 2. Properties.

Our principal executive offices are currently located at 1185 Avenue of the Americas, 3rd Floor, New York, New York 10036, where we lease approximately 300 square feet of general office space for a total cost of approximately $5,900 per month. The lease for

this office space expires on June 30, 2025 and is renewable for successive one year terms. We believe that our facilities are suitable and adequate for our needs for the foreseeable future.

Item 3. Legal Proceedings.

There are no legal proceedings against the Company and the Company is unaware of any such proceedings contemplated against it.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information and Holders

Our Common Stock is listed on Nasdaq under the symbol "SNPX." On March 25, 2025, the last reported sale price of our Common Stock was $2.64 per share.

As of March 25, 2025, we had 1,389,815 shares of our Common Stock issued and outstanding held by approximately 362 stockholders of record, based on information provided by our transfer agent. To date, we have not paid dividends on our Common Stock.

Unregistered Sales of Securities

On March 7, June 7, September 10 and December 9, 2024, we issued 981, 1,079, 1,304 and 1,552 restricted shares of our common stock, respectively, to Neil Cataldi, our investor relations consultant, in exchange for investor relations services.

The foregoing transactions did not involve any underwriters or any public offering. The sale of the above securities was deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act (and Regulation D promulgated thereunder) or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering. The recipients of the securities in the transaction represented their intentions to acquire the securities for investment only and not with a view to, or for sale in connection with, any distribution thereof, and appropriate legends were affixed to the securities issued in these transactions. All recipients received or had, through their relationships with us, adequate access to information about us.

Issuer Purchases of Equity Securities

None.

Item 6. [Reserved].

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing elsewhere in this report. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors."

The following discussion highlights our results of operations and the principal factors that have affected our financial condition as well as our liquidity and capital resources for the periods described, and provides information that management believes is relevant for an assessment and understanding of the statements of financial condition and results of operations presented herein. The following discussion and analysis are based on the audited financial statements contained in this report, which we have prepared in accordance

with United States generally accepted accounting principles. You should read the discussion and analysis together with such financial statements and the related notes thereto.

Basis of Presentation

The audited financial statements for the fiscal years ended December 31, 2024 and 2023 include a summary of our significant accounting policies and should be read in conjunction with the discussion below and our financial statements and related notes included elsewhere in this Annual Report on Form 10-K. In the opinion of management, all material adjustments necessary to present fairly the results of operations for such periods have been included in the financial statements. All such adjustments are of a normal recurring nature.

Overview

We are a biopharmaceutical company with product candidates in pre-clinical and clinical development. We began operations in October 2012. We are principally focused on developing a product platform based upon a drug candidate called Bryostatin-1 for the treatment of Alzheimer's disease, which is in the clinical testing stage. We are also evaluating Bryostatin-1 for other neurodegenerative or cognitive diseases and dysfunctions, such as Fragile X syndrome, MS, and Niemann-Pick Type C disease, which have undergone pre-clinical testing.

Neurotrope, our predecessor company, had been a party to a technology license and services agreement with the original Blanchette Rockefeller Neurosciences Institute (which has been known as Cognitive Research Enterprises, Inc. since October 2016), and its affiliate NRV II, LLC, which we collectively refer to herein as "CRE," pursuant to which we now have an exclusive non-transferable license to certain patents and technologies required to develop our proposed products. We were formed for the primary purpose of commercializing the technologies initially developed by BRNI for therapeutic applications for AD or other cognitive dysfunctions. These technologies have been under development by BRNI since 1999 and, until March 2013, had been financed through funding from a variety of non-investor sources (which include not-for-profit foundations, the NIH, which is part of the U.S. Department of Health and Human Services, and individual philanthropists). From March 2013 forward, development of the licensed technology has been funded principally through us in collaboration with CRE.

November 2022 Private Placement

On November 17, 2022, we entered into the November Purchase Agreement with the November Investors, pursuant to which we agreed to sell to the November Investors (i) an aggregate of 15,000 shares of Series B Preferred Stock and (ii) warrants to acquire up to an aggregate of 77,420 shares of Common Stock. We received total gross proceeds of approximately $15 million from the Series B Offering.

The Series B Preferred Stock matured on September 9, 2024, and no shares of Series B Preferred Stock remain outstanding. The terms of the Series B Preferred Stock were as set forth in the Certificate of Designations of Series B Convertible Preferred Stock (the "Series B Certificate of Designations"). We were required to redeem the Series B Preferred Stock in 15 equal monthly installments, commencing on June 1, 2023 and we issued an aggregate of 1,042,027 shares of Common Stock to redeem the Series B Preferred Stock.

The holders of the Series B Preferred Stock were entitled to dividends of 7% per annum, compounded monthly, which were payable in cash or shares of Common Stock at our option, in accordance with the terms of the Series B Certificate of Designations.

Notwithstanding the foregoing, the Company's ability to settle conversions and make amortization payments using shares of Common Stock was subject to certain limitations set forth in the Series B Certificate of Designations, including a limit on the number of shares that may be issued until the Nasdaq Stockholder Approval. The Company received Nasdaq Stockholder Approval at the Company's special meeting of stockholders held on April 14, 2023.

The Series B Warrants are exercisable for Series B Warrant Shares at an initial exercise price of $2.8586 per share (as adjusted from time to time pursuant to the terms of the Series B Warrants, the "Series B Exercise Price") and expire five years from the date of issuance. The Series B Exercise Price was reduced based upon the Reverse Stock Split and the Series C Private Placement (see below). The Series B Exercise Price is subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment, on a "full ratchet" basis, in the event of any issuances of Common Stock, or securities convertible,

exercisable or exchangeable for Common Stock, at a price below the then-applicable Series B Exercise Price (subject to certain exceptions).

During the year ended December 31, 2024, we redeemed $6,000,000 of the Series B Preferred Stock and $396,640 of accrued dividends through a combination of cash through installment redemption and by issuing 374,219 shares of our Common Stock through installment conversions and proportionately relieved $4,911,312 of discount related to the redeemed Series B Preferred Stock. During the year ended December 31, 2024, we recognized a deemed dividend of 271,086 related to cash premiums.

During the year ended December 31, 2023, we redeemed $9,000,000 of the Series B Preferred Stock and $1,022,149 of accrued dividends through a combination of cash through installment redemption and by issuing 585,908 shares of our Common Stock through installment conversions and proportionately relieved $7,366,968 of discount related to the redeemed Series B Preferred Stock. During the year ended December 31, 2023, we recognized a deemed dividend of $140,374 related to cash premiums and issued 81,901 shares of our Common Stock in satisfaction of the deemed dividend.

September 2024 Private Placement

On September 10, 2024, we entered into the Series C Purchase Agreement with the Series C Investors, pursuant to which we agreed to sell to the Series C Investors (i) in a registered direct offering, an aggregate of 1,793 shares of Series C Preferred Stock, initially convertible into up to 448,250 Registered Conversion Shares and (ii) in a concurrent private placement, an aggregate of 3,207 shares of Series C Preferred Stock, initially convertible into up to 801,750 Unregistered Conversion Shares as well as Series C Warrants to acquire up to an aggregate of 1,250,000 Series C Warrant Shares.

GP Nurmenkari Inc. acted as the placement agent (the "Series C Placement Agent"). In connection with the Series C Offering, pursuant to an engagement letter between the Company and the Series C Placement Agent, we agreed to pay the Series C Placement Agent (i) a cash fee equal to 7.0% of the gross proceeds from any sale of securities in the Series C Offering and (ii) warrants to purchase shares of Common Stock equal to 3.0% of the number of shares of Common Stock that the Series C Preferred Stock are initially convertible into, with an exercise price of $4.00 per share and a five-year term.

The terms of the Series C Preferred Stock are as set forth in the Certificate of Designations of the Series C Convertible Preferred Stock (the "Series C Certificate of Designations"), which was filed with the Secretary of State for the State of Delaware on September 12, 2024. The Series C Preferred Stock is convertible into Series C Conversion Shares at the election of the holder at any time at the Series C Conversion Price. The Series C Conversion Price is subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable Series C Conversion Price (subject to certain exceptions). We are required to redeem the Series C Preferred Stock in equal quarterly installments, commencing on October 31, 2024. The amortization payments due upon such redemption are payable in cash at 107% of the applicable Installment Amount (as defined in the Series C Certificate of Designations).

The holders of the Series C Preferred Stock are entitled to dividends of 5% per annum, compounded quarterly, which will be payable in cash. Upon the occurrence and during the continuance of a Triggering Event (as defined in the Series C Certificate of Designations), the Series C Preferred Stock will accrue dividends at the rate of 15% per annum. The holders of Series C Preferred Stock are entitled to vote with holders of the Common Stock as a single class on all matters that holders of Common Stock are entitled to vote upon, with the number of votes per Series C Preferred Stock equal to the stated value of such Series C Preferred Stock divided by the "Minimum Price" (as defined in Rule 5635 of the Listing Rules of the Nasdaq Stock Market) immediately prior to the date of the Series C Purchase Agreement.

Following the first anniversary of the initial issuance of the Series C Preferred Stock through the date that is ten calendar days thereafter, holders of Series C Preferred Stock may require the Company to redeem all or any portion of their Series C Preferred Stock in cash, pursuant to the terms set forth in the Series C Certificate of Designations.

The Company received Nasdaq Stockholder Approval at the Company's special meeting of stockholders held on December 6, 2024.

The Series C Certificate of Designations includes certain Triggering Events (as defined in the Series C Certificate of Designations), including, among other things, the failure to file and maintain an effective registration statement covering the sale of the holder's securities registrable pursuant to the Series C Registration Rights Agreement (defined below) and our failure to pay any amounts due to the holders of the Series C Preferred Stock when due. In connection with a Triggering Event, each holder of Series C Preferred Stock will be able to require us to redeem in cash any or all of the holder's Series C Preferred Stock at a premium set forth in the Series C Certificate of Designations.

We are subject to certain affirmative and negative covenants regarding the incurrence of indebtedness, acquisition and investment transactions, the existence of liens, the repayment of indebtedness, the payment of cash in respect of dividends (other than dividends pursuant to the Series C Certificate of Designations), distributions or redemptions, and the transfer of assets, among other matters.

The Series C Warrants are exercisable immediately at the Series C Exercise Price and expire five years from the date of issuance. The Series C Exercise Price is subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment, on a "full ratchet" basis, in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable Series C Exercise Price (subject to certain exceptions). There is no established public trading market for the Series C Warrants and we do not intend to list the Series C Warrants on any national securities exchange or nationally recognized trading system.

In connection with the Series C Purchase Agreement, on September 10, 2024, we and the Series C Investors entered into a registration rights agreement, pursuant to which we were required to file a resale registration statement with the SEC to register for resale 200% of the Unregistered Conversion Shares and 200% of the Series C Warrant Shares. We filed a registration statement for the resale of such securities on October 10, 2024, which was declared effective by the SEC on October 21, 2024. We also agreed to other customary obligations regarding registration, including indemnification and maintenance of the effectiveness of the registration statement.

During the year ended December 31, 2024, we redeemed $715,000 of the Series C Preferred Stock and $86,694 of accrued dividends in cash through installment redemption and proportionately relieved $1,592,341 of discount related to the redeemed Series C Preferred Stock. During the year ended December 31, 2024, we recognized a deemed dividend of $52,447 related to cash premiums.

As of December 31, 2024, we have accrued a liability for installment payments owed to investors in either cash or shares of $0.

Recent Developments

Exploring Strategic Alternatives

In December 2024, we announced via press release that the board of directors of the Company (the "Board") had formed an independent special committee (the "Special Committee") to explore strategic opportunities to create and enhance value for investors, including promising drug development platforms and/or compelling new technologies and services. Management has reviewed the Company's financial position and has concluded that the Company's continuing financial strength offset by anticipated future cash burn rate and publicly traded stock as currency allows the Special Committee to evaluate potential strategic opportunities.

Reverse Stock Split

On April 24, 2023, the Company received a written notice from the Listing Qualifications Department of the Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that for the preceding 30 consecutive business days, the Common Stock did not maintain a minimum closing bid price of $1.00 per share as required by Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company received an initial grace period of 180 calendar days, or until October 23, 2023 (the "Initial Compliance Period"), to regain compliance with the Minimum Bid Price Requirement. On October 24, 2023, the Company received a second written notice from Nasdaq, notifying the Company that it had not regained compliance with the Minimum Bid Price Requirement during the Initial Compliance Period and granting the Company an additional grace period of 180 calendar days, or until April 22, 2024, to regain compliance. On April 4, 2024, the Company effected a one - for - twenty - five reverse stock split of the Common Stock (the "Reverse Stock Split") in order to regain compliance with the Minimum Bid Price Requirement.

On April 22, 2024, Nasdaq informed the Company that it had regained compliance with the Minimum Bid Price Requirement and that the matter was closed.

Results of Most Recent Extended Confirmatory Phase 2 Clinical Trial

On July 23, 2020, we entered into the 2020 Services Agreement with WCT. The 2020 Services Agreement relates to services for our Phase 2 clinical study assessing the safety, tolerability and long-term efficacy of Bryostatin-1 in the treatment of moderately severe AD subjects not receiving memantine treatment. On January 22, 2022, we executed a change order with WCT to accelerate trial subject recruitment totaling approximately $1.4 million. The updated total estimated budget for the services, including pass-through costs, is approximately $11.0 million. As previously disclosed, on January 22, 2020, we were granted a $2.7 million award from the NIH, which award is being used to support the 2020 Study, resulting in a current estimated net budgeted cost of the 2020 Study to us of $8.3 million. Of the $2.7 million grant, virtually all has been received as of February 22, 2022. The 2020 Study was completed in December 2023.

On December 16, 2022, we issued a press release announcing that an extended confirmatory Phase 2 study of Bryostatin-1 in moderate to severe AD (Study #204) did not achieve statistical significance on the primary endpoint, which was change from baseline to week 13 in the SIB total score assessment obtained after completion of the second seven-dose course of treatment (week 28 of trial). An average increase in the SIB total score of 1.4 points and 0.6 points was observed for the Bryostatin-1 and placebo groups, respectively, at week 28. On March 7, 2023, we announced the results of our analysis of secondary endpoints and post hoc analysis from our Phase 2 study of Bryostatin-1. In the secondary endpoint analysis, changes from baseline at Weeks 9, 20, 24, 30, and 42 in the SIB (Severe Impairment Battery) total score were not statistically significant in the total patient population, and no pre-specified secondary endpoints were met with statistical significance in the low-to-moderately severe AD patient stratum. However, nearly all pre-specified secondary endpoints in the most advanced and severe AD (MMSE: 10-14) patient population, with baseline MMSE-2 (Mini-Mental State Examination, 2nd Edition) scores of 10-14, were achieved with statistical significance ($p = <0.05$, 2-tailed). Data also showed statistical significance in exploratory secondary endpoints for the MMSE-2 10-14 stratum, and post hoc analysis was positive. We are continuing to determine next steps with the development of Bryostatin-1 for AD as well as for other potential indications, including in tandem with promising drug development platforms.

As of December 31, 2024, we incurred cumulative expenses of approximately $11.3 million associated with services provided by WCT and certain pass-through expenses incurred by WCT, which was offset by NIH reimbursements recognized of $2.7 million. No expenses were incurred for the year ended December 31, 2024. For the year ended December 31, 2023, we incurred expenses of approximately $560,000 million associated with services provided by WCT and certain pass-through expenses incurred by WCT.

Open Label Dose Ranging Clinical Trial

On May 12, 2022, the Company entered into a services agreement with WCT (the "2022 Services Agreement"). The 2022 Services Agreement relates to services for a Phase 2 "open label," dose ranging study, clinical trial assessing the safety, tolerability and efficacy of Bryostatin-1 administered via infusion in the treatment of moderately severe to severe AD subjects not receiving memantine treatment (the "2022 Study").

Pursuant to the terms of the 2022 Services Agreement, WCT provided services to enroll approximately 12 2022 Study subjects. The first 2022 Study site was initiated during the third quarter of 2022. The total estimated budget for the services, including pass-through costs, was approximately $2.0 million. The Company terminated the 2022 Services Agreement in December 2022.

The Company incurred cumulative expenses of approximately $1.6 million associated with the 2022 Study as of December 31, 2024. $0 of the expenses are reflected in the statement of comprehensive loss for the year ended December 31, 2024 and approximately $200,000 is reflected in the statement of comprehensive loss for the year ended December 31, 2023.

Other Development Projects

To the extent resources permit, we may pursue development of selected technology platforms with indications related to the treatment of various disorders, including neurodegenerative disorders such as AD, based on our currently licensed technology and/or technologies available from third party licensors or collaborators.

Nemours Agreement

On September 5, 2018, we announced a collaboration with Nemours, a premier U.S. children's hospital, to initiate a clinical trial in children with Fragile X. In addition to the primary objective of safety and tolerability, measurements will be made of working memory, language and other functional aspects such as anxiety, repetitive behavior, executive functioning, and social behavior. On August 5, 2021, the Company announced its memorandum of understanding with Nemours A.I. DuPont Hospital ("Nemours") to initiate a clinical trial using Bryostatin-1, under Orphan Drug Status, to treat Fragile X. The Company intends to provide the Bryostatin-1 drug product candidate and obtain the investigational new drug documentation ("IND") and Nemours intends to provide the clinical site and attendant support for the trial. The Company and Nemours, jointly, will develop the trial protocol. The Company currently estimates its total trial and IND cost to be approximately $2 million. As of the end of the period covered by this annual report, the Company has incurred cumulative expenses associated with this agreement of approximately $100,000.

We have filed for an IND with the FDA. The FDA has placed the development of the IND on clinical hold pending completion of further analytics relating to drug pharmacokinetics and pharmacodynamics. The Company is currently evaluating its plans to advance Fragile X development.

Cleveland Clinic

On February 23, 2022, we announced our collaboration with the Cleveland Clinic to pursue possible treatments for Multiple Sclerosis ("MS"), and on July 19, 2023, we announced that we had entered into an agreement with the Cleveland Clinic to conduct a Phase 1 trial of Bryostatin-1 in MS. Pursuant to the agreement, the Cleveland Clinic was obligated to manage the clinical trial's implementation, including the IND submission to the FDA which was filed during the fourth quarter of 2023 and future patient enrollment upon approval of the IND submission. The total estimated costs associated with this collaboration are approximately $2.0 million. As of December 31, 2024, the Company has paid or incurred costs with the Cleveland Clinic of approximately $528,000.

In December 2024, the Company announced via press release the termination of its agreement with the Cleveland Clinic due to the slow pace of enrollment in the Phase 1 clinical trial. The termination of the agreement was one of various actions authorized by the Board, designed to reduce cash burn rate.

Strategic Investment

Strategic Investment in Debt and Equity Securities of Cannasoul

On October 31, 2023, the Company entered into a share purchase agreement (the "Purchase Agreement") with Cannasoul Analytics Ltd. ("Cannasoul"), pursuant to which the Company agreed to purchase from Cannasoul (i) 12,737 shares of Cannasoul's Series A preferred shares (the "Preferred Shares"), representing 5% of Cannasoul's issued and outstanding share capital, at a price of $44.1550 per Preferred Share for $562,402 and (ii) a convertible preferred note in an aggregate amount of up to $1,437,598 (the "Initial Convertible Note") convertible into 32,648 Preferred Shares. The Preferred Shares are convertible (i) any time after the date of issuance at the Company's option and (ii) automatically upon the earlier of a payment default, the consummation of Cannasoul's IPO, or the majority consent of the majority holders of the Preferred Shares.

Additionally, the Company agreed to purchase up to four additional convertible preferred notes in a total amount of up to approximately $2,000,000 (or approximately $500,000 per convertible preferred note), subject to Cannasoul achieving certain revenue and expense goals (the "Milestones") over the next four quarters (the "Milestone Convertible Notes") as set forth in the Purchase Agreement. The Company's purchase of the Preferred Shares, the Initial Convertible Notes and the Milestone Convertible Notes is herein referred to as the "Investment." If Cannasoul fails to achieve a Milestone, the Company will not be obligated to purchase the applicable Milestone Convertible Note. If Cannasoul achieves a Milestone and the Company fails to purchase the applicable Milestone Convertible Note, Cannasoul will have the right to convert all the Company's Preferred Shares into Cannasoul's ordinary shares and the Company will lose certain board appointment rights and certain rights in Cannasoul's subsidiaries.

In connection with the Purchase Agreement, Cannasoul adopted amended and restated articles of incorporation (the "Cannasoul Charter"). Pursuant to the Cannasoul Charter, the Company has a number of rights as investor, including (i) the right to appoint and dismiss three of the seven members of Cannasoul's board of directors and veto power with respect to a fourth member, (ii) preemptive rights to participate pro rata in any pre-initial public offering financings by Cannasoul, (iii) rights of first refusal with respect to transfers of Cannasoul ordinary shares by other investors, (iv) rights of co-sale with respect to proposed sales or transfers of Cannasoul ordinary shares by certain key investors, (v) veto rights with respect to certain major transactions, any amendment to the Cannasoul Charter, approval of Cannasoul's budget and other items.

The Company's investment in the Preferred Shares represents an investment in an equity security in accordance with ASC 320. The Preferred Shares are convertible at any time after the date of issuance, automatically upon a payment default, an IPO, or the written consent of the holders of a majority of the Preferred Shares. The conversion price is subject to traditional anti-dilution adjustments. The Company will account for its investment in Cannasoul's Preferred Shares under the equity method of accounting as it was determined the Company has significant influence over Cannasoul based on its board representation and other veto rights per ASC 323-10-15-6 to 8. The Company has elected to record the equity in earnings of the equity method investment on a three-month lag which is recognized in other comprehensive income. As a result, the Company has not recorded a gain or loss on its equity method investment during the year ended December 31, 2023.

Dr. David (Dedi) Meiri, founder of Cannasoul, heads the Laboratory of Cancer Biology and Cannabinoid Research at the Technion, where he develops cannabinoids for various indications. Pursuant to a license agreement between Cannasoul, Dr. Meiri and Technion, Cannasoul has a right of first look with respect to each new cannabinoid indication developed in Dr. Meiri's laboratory and not otherwise funded by a third party. Whenever Cannasoul exercises this right of first look, it creates a new Project Subsidiary to carry out the development of such indication. In connection with the Investment, the Company received certain rights in existing Project Subsidiaries. Additionally, Cannasoul granted the Company a right of first look to invest in any new Project Subsidiaries as well as certain preemptive and veto rights in connection with such Project Subsidiaries. Pursuant to the Collaboration Agreement, the parties agreed to form the JRC. The JRC will evaluate the technology and compounds developed by Dr. Meiri in his laboratory, assess the feasibility of developing and commercializing each compound and, for those compounds with respect to which we exercise our right of first look, collaborate on the strategy for clinical development of such compounds.

Also on October 31, 2023, we entered into the Investor Rights Agreement. Pursuant to the Investor Rights Agreement, if Cannasoul ever completes an initial public offering in the United States, we and certain other investors in Cannasoul may, subject to conditions set forth in the Investor Rights Agreement, request that Cannasoul file a registration statement with the U.S. Securities and Exchange Commission covering the resale of the ordinary shares underlying the Cannasoul Preferred Shares.

As of December 31, 2024, the Company determined that its investment in Cannasoul had a valuation of $0 based upon its disposition of its assets and limited minority ownership in other related technologies. As a result, the Company has written off its related debt and equity investments.

Results of Operations

Comparison of the years ended December 31, 2024 and 2023

The following table summarizes our results of operations for the years ended December 31, 2024 and 2023:

	Years ended December 31,		Dollar	
	2024	2023	Change	% Change
Operating Expenses:				
Research and development expenses	$ 1,598,722	$ 1,974,924	$ (376,202)	(19.0)%
General and administrative expenses	$ 5,212,010	$ 6,338,930	$ (1,126,920)	(17.8)%
Other income (loss), net	$ (5,957,817)	$ 2,275,350	$ (8,233,167)	(361.8)%
Net loss	$ 12,768,549	$ 6,038,504	$ 6,730,045	111.5 %

Revenues

We did not generate any operating revenues for the years ended December 31, 2024 and 2023.

Operating Expenses

Overview

Total operating expenses for the year ended December 31, 2024 were $6,810,732 as compared to $8,313,854 for the year ended December 31, 2023, a decrease of approximately 18.1%. The decrease in total operating expenses is due to the decrease in both research and development and general and administrative expenses.

Research and Development Expenses

For the year ended December 31, 2024, we incurred $1,598,722 in research and development expenses as compared to $1,974,924 for the year ended December 31, 2023, a decrease of approximately 19.0%. These expenses were incurred primarily in connection with developing the potential AD therapeutic product and the initiation of the MS trial with Cleveland Clinic. Of these expenses, for the year ended December 31, 2024, $900,655 was incurred principally relating to our current MS clinical trial and our storage of drug product, $634,713 for clinical consulting services, $29,669 of amortization of prepaid licensing fees relating to the Stanford License Agreement and Mount Sinai Agreement, $33,685 for development of alternative drug supply with Stanford University; comparatively, for the year ended December 31, 2023, $1,440,207 was incurred principally relating to our confirmatory clinical trial and related storage of drug product, $312,743 for clinical consulting services, $20,330 of amortization of prepaid licensing fees relating to the Stanford License Agreement and Mount Sinai Agreement, $52,055 for development of alternative drug supply with Stanford University and $149,589 of non-cash stock options compensation expense.

Our research and development expenses have decreased as our Phase 2 clinical trial for AD was concluded by the end of 2023 and our Phase 2 dose ranging study was discontinued while we initiated our MS clinical trial. Other development expenses might increase, as our resources permit, in order to advance our potential products. We are continuing to determine how to proceed with respect to our other current development programs for Bryostatin-1.

General and Administrative Expenses

We incurred $5,212,010 and $6,338,930 of general and administrative expenses for the year ended December 31, 2024 and 2023, respectively, a decrease of approximately 17.8%. During the year ended December 31, 2024, $1,763,731 was incurred primarily for wages, bonuses, vacation pay, severance, taxes and insurance, versus $1,555,462 for the year ended December 31, 2023, the increase resulted primarily from compensation paid to strategic committee members of the Board of Directors for extensive new business due diligence; $561,114 was incurred for legal expenses versus $814,198 for the 2023 comparable period. The higher legal fees for 2023 is based upon the prior year's increased fees for special stockholder meeting requirements and for regulatory compliance; $974,685 was incurred for outside operations consulting services during the year ended December 31, 2024, versus $989,177 for the comparable period

in 2023; $102,336 was incurred for travel expenses during the year ended December 31, 2024, versus $150,564 for the comparable period in 2023 as Company officers and directors conducted overseas due diligence for strategic investments in 2023; $464,025 was incurred for investor relations services during the year ended December 31, 2024, versus $436,593 for the comparable period in 2023; $261,988 was incurred for professional fees associated with auditing, financial, accounting and tax advisory services during the year ended December 31, 2024, versus $297,090 for the comparable period in 2023; $620,436 was incurred for insurance during the year ended December 31, 2024, versus $769,175 for the comparable period in 2023. The decrease is attributable to lower premiums; $438,288 was incurred for utilities, supplies, license fees, filing costs, rent, advertising and other during the year ended December 31, 2024, versus $466,935 for the comparable period in 2023. The decrease is attributable to credits for franchise taxes paid during the 2023 period credited to 2024; and $25,407 was recorded as non-cash stock options compensation expense during the year ended December 31, 2024, versus $859,736 for the comparable period in 2023, as options granted during the 2023 period partially vested upon issuance.

Other Income / Expense

We recognized total other losses of $5,957,817 for the year ended December 31, 2024 as compared to total other income of $2,275,350 for the year ended December 31, 2023, which consisted, for 2024 and 2023, of interest income on funds deposited in interest-bearing money market accounts and investments in short-term U.S. treasury bills and changes in fair value of warrant and derivative liabilities and offering costs. The decrease in interest income and unrealized gains on treasury bills totaling $373,065 for the year ended December 31, 2024 is primarily attributable to the decrease in cash balances over the period and lower interest rates. The total decreased income is primarily attributable to the loss on write off of available for debt security of $2,443,300, loss on write off of equity investment of $517,877, both due to the complete write-down of our Cannasoul investment, increase in change in fair value of warrant liability of $829,000, loss on issuance of Series C Preferred Stock of $3,812,625 million, warrant issuance costs of $618,375 and share of loss in equity investment and investment write-off totaling $562,402 partially offset by the change in fair value of derivative liability of $1,032,000.

Net loss

We recognized losses of $12,768,549 and $6,038,504 for the year ended December 31, 2024 and 2023, respectively. The increased loss was primarily attributable to the increase in other loss partially offset by the decrease in research and development and general and administrative expenses.

Financial Condition, Liquidity and Capital Resources

Cash and Working Capital

Since inception, we have incurred negative cash flows from operations. As of December 31, 2024, we had working capital of $16,706,587 as compared to working capital of $26,256,291 as of December 31, 2023. The $9,549,704 decrease in working capital was primarily attributable to approximately $6.9 million of operating expenses, redemptions of Series B Preferred Stock of approximately $8.8 million and redemption of Series C Preferred Stock of approximately $800,000 partially offset by net proceeds from Series C Preferred Stock offering of approximately $4.5 million, non-cash expenses of approximately $1.0 million and interest income of approximately $1.3 million.

We expect that our current cash and cash equivalents of approximately $15 million will be sufficient to support our projected operating requirements for at least the next 12 months from the date of this Annual Report on Form 10-K, which may include the continuing development of Bryostatin-1, our initiation and possible development of a therapeutic for MS and other possible therapeutics.

We expect to require additional capital in order to initiate, pursue and complete all potential AD clinical trials and obtain regulatory approval of one or more therapeutic candidates. However, additional future funding may not be available to us on acceptable terms, or at all. If we are unable to access additional funds when needed, we may not be able to initiate, pursue and complete all planned clinical trials or continue the development of our product candidates or we could be required to delay, scale back or eliminate some or all of our development programs and operations. Any additional equity financing, if available, may not be available on favorable terms, would most likely be significantly dilutive to our current stockholders and debt financing, if available, and may involve restrictive covenants. If we are able to access funds through collaborative or licensing arrangements, we may be required to relinquish rights to some of our technologies or product candidates that we would otherwise seek to develop or commercialize on our own, on terms that

are not favorable to us. Our ability to access capital when needed is not assured and, if not achieved on a timely basis, would likely materially harm our business and financial condition.

Sources and Uses of Liquidity

We expect to continue to incur expenses, resulting in losses and negative cash flows from operations, over at least the next several years as we continue to develop AD and other therapeutic products. We anticipate that this development may include clinical trials in addition to our current ongoing clinical trial and additional research and development expenditures.

	Year Ended December 31,	
	2024	2023
Cash used in operating activities	$ 4,883,988	$ 5,173,209
Cash used in investing activities	$ 1,000,000	$ 2,002,707
Cash used in financing activities	$ 5,121,289	$ 1,641,066

Net Cash Used in Operating Activities

Cash used in operating activities was $4,883,988 for the year ended December 31, 2024, compared to $5,173,209 for the year ended December 31, 2023. The $289,221 decrease primarily resulted from the increase in offering costs of approximately $4.4 million, losses from the write-off of the Cannasoul strategic investment of approximately $3.0 million, the decrease in prepaid expenses of approximately $0.3 million, and the changes in fair value of non-cash warrant and derivative liabilities totaling approximately $0.2 million partially offset by the increased net loss of approximately $6.7 million, and increase in accrued expenses of approximately $0.5 million and the decrease in non-cash stock-based compensation and consulting fees of approximately $1.0 million.

Net Cash Used in Investing Activities

Net cash used in investing activities was $1.0 million for the year ended December 31, 2024 compared to $2,002,707 for the year ended December 31, 2023. The cash used in investing activities for the year ended December 31, 2024 was for the purchase of available for sale debt securities versus capital expenditures for the year ended December 31, 2023.

Net Cash Used in / Provided by Financing Activities

Net cash used in financing activities was $5,121,289 for the year ended December 31, 2024 compared to $1,641,066 for the year ended December 31, 2023 which consists primarily of redemptions of amounts due to preferred stock investors.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act, and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data.

Our audited financial statements as of, and for the years ended December 31, 2024 and December 31, 2023 are included beginning on Page F-1 immediately following the signature page to this report. See “Item 15. Exhibits and Financial Statement Schedules” for a list of the financial statements included herein.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of December 31, 2024. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered in this report, because of certain weaknesses in internal control over financial reporting discussed below under "Management's Annual Report on Internal Control over Financial Reporting," our disclosure controls and procedures were not effective to ensure that information required to be disclosed in reports filed by us under the Exchange Act is recorded, processed, summarized and reported within the required time periods and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all errors or fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Due to the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Management believes that the financial statements included in this report fairly present in all material respects our financial condition, results of operations and cash flows for the periods presented.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect all misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Because of the inherent limitations of internal control, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

As of December 31, 2024, our management, including our Chairman of the Board, principal executive officer and principal financial officer, assessed the effectiveness of our internal control over financial reporting based on the criteria for effective internal control over financial reporting established in the 2013 Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") and SEC guidance on conducting such assessments. Based on that evaluation, they concluded that, as of December 31, 2023, such internal controls and procedures were not effective. This was due to deficiencies that existed in the design or operation of our internal controls over financial reporting that are considered to be material weaknesses. The matters involving internal controls and procedures that our management considered to be material weaknesses were:

1. inadequate segregation of duties consistent with control objectives in the areas over certain user access controls; and

2. ineffective processes over period end financial disclosure and reporting including documentation of GAAP disclosure and reporting reviews supporting the financial reporting process; and

3. ineffective information technology (IT) general computing controls including lack of risk and design assessments such as IT security policies and procedures, user access, review and assessment of IT controls within third party contracts.

The material weaknesses and significant deficiency did not result in any identified misstatements to the financial statements and there were no changes to previously released financial results.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act, which permits us to provide only management's report in this Annual Report on Form 10-K.

Management's Remediation Initiatives

In an effort to remediate identified material weaknesses and other deficiencies and enhance our internal controls, we increased certain measures including additional cash controls, closer supervision of outside service providers and other review and approval processes by our management team. The remediation efforts will further include the implementation of additional controls to ensure all risks have been addressed. Preparation of a GAAP disclosure checklist with appropriate review procedures to ensure that accounting guidance and disclosure requirements have been addressed. We will, as resources permit, hire additional personnel to allow for segregation of duties.

If we are unsuccessful in implementing our remediation plan, or fail to update our internal control over financial reporting as our business evolves or to integrate acquired businesses into our controls system, if additional material weaknesses are found, we may not be able to timely or accurately report our financial condition, results of operations or cash flows or to maintain effective disclosure controls and procedures. If we are unable to report financial information in a timely and accurate manner or to maintain effective disclosure controls and procedures, we could be subject to, among other things, regulatory or enforcement actions by the SEC, an inability for us to be accepted for listing on any national securities exchange in the near future, securities litigation and a general loss of investor confidence, any one of which could adversely affect our business prospects and the market value of our Common Stock. Further, there are inherent limitations to the effectiveness of any system of controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. We could face additional litigation exposure and a greater likelihood of an SEC enforcement or other regulatory action if further restatements were to occur or other accounting-related problems emerge.

The weaknesses will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

Changes in Internal Control Over Financial Reporting

Except as discussed above under "Management's Remediation Initiatives," there were no changes in our internal control over financial reporting identified in connection with the evaluation referred to above that occurred during our last completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Matters affecting our internal controls may cause us to be unable to report our financial information on a timely basis or may cause us to restate previously issued financial information, and thereby subject us to adverse regulatory consequences, including sanctions or investigations by the SEC, or violations of applicable stock exchange listing rules.

Item 9B. Other Information.

(b) During the three months ended December 31, 2024, no director or officer of the Company adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers and Directors

The following table lists the names, ages and positions of our executive officers as of March 25, 2025:

Name	Age	Position
Alan J. Tuchman, M.D.	78	Chief Executive Officer
Robert Weinstein	65	Chief Financial Officer, Secretary and Executive Vice President
Daniel L. Alkon, M.D.	82	President, Chief Scientific Officer

Alan J. Tuchman, M.D. — Chief Executive Officer. Dr. Tuchman joined Synaptogenix as our Chief Executive Officer in December 2020. He is also currently Clinical Professor of Neurology at New York Medical College and managed a private practice of Neurology in Manhattan until June 2024. He consults for a number of biotechnology and investment firms. Dr. Tuchman founded and was Managing Director of MedPro Investors LLC from 2011 to 2020. He has served as a partner of Xmark Opportunity Partners and as CEO and then Executive Chairman of Neurophysics, Inc. from 2002 to 2010. Dr. Tuchman served as Senior Vice President and Chief Medical Officer of Oncolytics Biotech Inc. from 2012 to 2017. He was previously the President of the Epilepsy Society of Southern New York as well as Vice Dean for Clinical Affairs at New York Medical College. Dr. Tuchman received his MD degree from the University of Cincinnati, College of Medicine, and completed his Neurology Residency at the Mt. Sinai School of Medicine. Dr. Tuchman received his MBA from Columbia University in 1996. He has authored over 30 scientific papers and book chapters.

Robert Weinstein — Chief Financial Officer, Executive Vice President, Treasurer and Secretary. Mr. Weinstein joined Neurotrope in June 2013 as its acting Chief Financial Officer and has continued to serve in that role for Synaptogenix following the Spin-Off. In addition, Mr. Weinstein performs work as a consultant for Petros Pharmaceuticals, Inc., which is the surviving company from the merger of Metuchen and Neurotrope. He has extensive accounting and finance experience, spanning more than 40 years, as a public accountant, investment banker, healthcare private equity fund principal and chief financial officer. From September 2011 to the present, Mr. Weinstein has been an independent consultant for several healthcare companies in the pharmaceutical and biotechnology industries. From March 2010 to August 2011, he was the Chief Financial Officer of Green Energy Management Services Holdings, Inc., an energy consulting company. From August 2007 to February 2010, Mr. Weinstein served as Chief Financial Officer of Xcorporeal, Inc., a development-stage medical device company which was sold in March 2010 to Fresenius Medical USA, the largest provider of dialysis equipment and services worldwide. Mr. Weinstein also serves as a member of the Board of Directors of Xwell, Inc. (Formerly XpresSpa Group, Inc.) (Nasdaq: XWEL), a health and wellness company whose core asset, XpresSpa, is a leading airport retailer of spa services and related health and wellness products, PharmaCyte Biotech, Inc. (Nasdaq: PMCB), a biotechnology company developing pharmaceutical products and Oblong, Inc. (Nasdaq: OBLG), a company that provides multi-stream collaboration technologies and managed services for video collaboration and network applications in the United States and internationally. Mr. Weinstein received his MBA degree in finance and international business from the University of Chicago Graduate School of Business, is a Certified Public Accountant (inactive), and received his BS degree in accounting from the State University of New York at Albany.

Daniel L. Alkon, M.D. — President and Chief Scientific Officer. Dr. Alkon was appointed as Neurotrope's President and Chief Scientific Officer (CSO) on September 16, 2016 and he has continued to serve in that role for Synaptogenix following the Spin-Off. He received his undergraduate degree in chemistry in 1965 at the University of Pennsylvania. After earning his M.D. at Cornell University and finishing an internship in medicine at the Mount Sinai Hospital in New York, he joined the staff of the National Institutes of Health where during his 30-year career he became a Medical Director in the U.S. Public Health Service at the National Institute for Neurological Disorders and Stroke and Chief of the Laboratory of Adaptive Systems. Dr. Alkon then served as the founding Scientific Director of the original Blanchette Rockefeller Neurosciences Institute (BRNI - now known as CRE) from 1999 until September 23, 2016. From October 2000 to September 28, 2016, Dr. Alkon was a Professor at BRNI and a Professor of Neurology at West Virginia University. From June 2006 to September 23, 2016, Dr. Alkon was also the Toyota Chair for Neurodegenerative Disease Research at BRNI (now CRE). From October 2000 to July 2005, Dr. Alkon was appointed as Research Professor in Biophysics at the Johns Hopkins University. In all of these positions, Dr. Alkon and his teams conducted multidisciplinary research on the molecular, biophysical, and synaptic-structural mechanisms of learning, memory storage, and memory dysfunction in psychiatric and neurological disorders, particularly Alzheimer's disease. Numerous patents were issued based on this research on memory that then was extended to drug development for the treatment of neurodegenerative disorders such as AD, Stroke, PTSD, Multiple Sclerosis, and Amyotrophic Lateral Sclerosis (ALS). As an internationally recognized authority on neural and artificial networks, he has co-authored hundreds of peer-reviewed articles as well as several books, including "Memory Traces in the Brain" (Cambridge University Press), and "Memory's Voice" (Harper Collins).

Board Structure and Directors

The below table sets forth information regarding our directors as of March 25, 2025:

Director	Age	Position	Date Named to Board of Directors
Joshua N. Silverman	54	Chairman of the Board of Directors	August 4, 2016
William S. Singer	84	Director; Vice-Chairman of the Board	August 23, 2013
Daniel L. Alkon, M.D.	82	Director	December 7, 2020
Bruce T. Bernstein	61	Director	November 14, 2016
Jonathan L. Schechter	51	Director	December 13, 2018
Alan J. Tuchman, M.D.	79	Director	December 7, 2020

Our Board is currently comprised of six members: Mr. Silverman, Mr. Singer, Mr. Bernstein, Mr. Schechter, Dr. Alkon and Dr. Tuchman.

The principal occupation and business experience during the past five years for our directors is as follows (other than our directors who are executive officers, whose principal occupation and business experience during the past five years is discussed above):

Joshua N. Silverman — Director, Chairman of the Board. Mr. Silverman joined Neurotrope as a Director and Chairman of the Board in August 2016. Mr. Silverman currently serves as the managing member of Parkfield Funding LLC. Mr. Silverman has also served as Interim Chairman, Interim Chief Executive Officer and Interim President of PharmaCyte Biotech, Inc. (Nasdaq: PMCB) since October 2022 and as a director since August 2022. Mr. Silverman was the co-founder, and a principal and managing partner of Iroquois Capital Management, LLC ("Iroquois"), an investment advisory firm. Since its inception in 2003 until July 2016, Mr. Silverman served as co-chief investment officer of Iroquois. While at Iroquois, he designed and executed complex transactions, structuring and negotiating investments in both public and private companies and has often been called upon by the companies solve inefficiencies as they relate to corporate structure, cash flow, and management. From 2000 to 2003, Mr. Silverman served as co-chief investment officer of Vertical Ventures, LLC, a merchant bank. Prior to forming Iroquois, Mr. Silverman was a director of Joele Frank, a boutique consulting firm specializing in mergers and acquisitions. Previously, Mr. Silverman served as assistant press secretary to the president of the United States. In addition to Synaptogenix, Mr. Silverman has served as a director and acting Chief Executive Officer of AYRO, Inc. (Nasdaq: AYRO) since 2020; as Interim Chief Executive Officer, Interim President and Interim Chairman of PharmaCyte Biotech, Inc. (Nasdaq: PMCB); as director of TNF Pharmaceuticals, Inc. (formerly known as MYMD Pharmaceuticals, Inc.) (Nasdaq: TNFA) since September 2018; and as Vice Chairman of Petros Pharmaceutical, Inc. (Nasdaq: PTPI). He previously served as a director of Marker Therapeutics, Inc. from 2016 until 2018 and Protagenic Therapeutics, Inc. from 2016 to 2022. Mr. Silverman received his B.A. from Lehigh University in 1992. Mr. Silverman was chosen as Chairman of Synaptogenix because of his lengthy public company, finance and business experience.

William S. Singer — Director and Vice-Chairman of the Board of Directors. Mr. Singer served as a Director and Vice-Chairman of the Board for Neurotrope since August 23, 2019. He was a partner in the Chicago office of the law firm of Kirkland & Ellis LLP from 1980 until 2006 and has been of counsel to that firm since that time, concentrating his practice on corporate, real estate, and legislative matters. Mr. Singer currently serves on the Board of Directors of the National Park Foundation. He was appointed by the Secretary of the Interior. Mr. Singer has been prominently active in Chicago public service, serving as an Alderman for several years and as a candidate for Mayor. Mr. Singer was chosen as a director of Synaptogenix because of his lengthy legal and public company experience.

Bruce T. Bernstein — Director. Mr. Bernstein served as a Director for Neurotrope since November 14, 2016. Mr. Bernstein has over thirty years of experience in the securities industry, primarily as senior portfolio manager for two alternative finance funds as well as in trading and structuring of arbitrage strategies. Mr. Bernstein has served as President of Rockmore Capital, LLC since 2006, the manager of a direct investment and lending fund with peak assets under management of $140 million. Previously, he served as Co-President of Omicron Capital, LP, an investment firm based in New York, which he joined in 2001. Omicron Capital focused on direct investing and lending to public small cap companies and had peak assets under management of $260 million. Prior to joining Omicron Capital, Mr. Bernstein was with Fortis Investments Inc., where he was Senior Vice President in the bank's Global Securities Arbitrage business unit, specializing in equity structured products and equity arbitrage and then President in charge of the bank's proprietary investment business in the United States. Prior to Fortis, Mr. Bernstein was Director in the Equity Derivatives Group at Nomura Securities International specializing in cross-border tax arbitrage, domestic equity arbitrage and structured equity swaps. Mr. Bernstein started his career at Kidder Peabody, where he rose to the level of Assistant Treasurer. Mr. Bernstein also serves as a member of the Board of Directors of Xwell, Inc. (Formerly XpresSpa Holdings, Inc.) (Nasdaq: XWEL) the leading airport spa company in the world, based in New York, Petros Pharmaceuticals, Inc. (Nasdaq: PTPI) and Wrap Technologies, Inc. (Nasdaq: WRAP). Mr. Bernstein holds a B.B.A. from City University of New York (Baruch). Mr. Bernstein was chosen as a director of Synaptogenix because of his lengthy public company and finance experience.

Jonathan L. Schechter — Director. Mr. Schechter joined our Board of Directors in December 2019. Mr. Schechter currently serves as a partner of The Special Equities Group, a division of Dawson James Securities, Inc., a full-service investment bank specializing in healthcare, biotechnology, technology, and clean-tech sectors, since April 2021. Mr. Schechter is one of the founding partners of The Special Equities Opportunity Fund, a long-only fund that makes direct investments in micro-cap companies and has served in this capacity since August 2019. He currently serves on the board of directors of Oblong, Inc., a technology company (Nasdaq: OBLG), and previously served as a director of DropCar, Inc. Mr. Schechter also serves as a member of the Board of Directors of PharmaCyte Biotech, Inc. (Nasdaq: PMCB), a biotechnology company developing pharmaceutical products. He has extensive experience analyzing and evaluating the financial statements of public companies. Mr. Schechter earned his A.B. in Public Policy/Political Science from Duke University and his J.D. from Fordham University School of Law. Mr. Schechter was chosen as a director of Synaptogenix because of his lengthy public company, legal and investment banking experience.

Director Independence

Our Board has reviewed the materiality of any relationship that each of our directors and director nominees has with the Company, either directly or indirectly. Based upon this review, our Board has determined that the following members of the Board and director nominees are "independent directors" as defined by The Nasdaq Stock Market:

Joshua N. Silverman
William S. Singer
Bruce T. Bernstein
Jonathan L. Schechter

Staggered Board

Our certificate of incorporation provides that our business is to be managed by or under the direction of our Board. Our Board is divided into three classes for purposes of election. One class is elected at each annual meeting of stockholders to serve for a three-year term. Our Board consists of six members classified into three classes as follows: (1) Alan Tuchman, M.D. and Daniel L. Alkon, M.D. constitute the Class II directors and their current terms will expire at the 2026 annual meeting of stockholders, (2) Joshua N. Silverman and William S. Singer constitute the Class III directors and their current terms will expire at the 2027 annual meeting of stockholders and (3) Bruce T. Bernstein and Jonathan L. Schechter constitute the Class I directors and their current terms will expire at the 2025 annual meeting of stockholders.

Board Committees

Our Board has established three committees, each of which is composed solely of independent directors:

- The Audit Committee consists of Mr. Bernstein, as Chairman, Mr. Singer and Mr. Schechter.
- The Compensation Committee consists of Mr. Silverman as Chairman, Mr. Bernstein and Mr. Singer.
- The Nominating and Corporate Governance Committee consists of Mr. Singer, as Chairman, Mr. Bernstein and Mr. Silverman.

Each of the Committees has a written charter adopted by the Board; a current copy of each such charter is available to security holders on our website, *http://www.synaptogen.com*.

Audit Committee

The Audit Committee (a) assists the Board in fulfilling its oversight of: (i) the quality and integrity of the Company's financial statements; (ii) the Company's compliance with legal and regulatory requirements relating to the Company's financial statements and related disclosures; (iii) the qualifications and independence of the Company's independent auditors; and (iv) the performance of the Company's independent auditors; and (b) prepares any reports that the rules of the SEC require be included in the Company's annual proxy statement.

The Audit Committee of Synaptogenix was established in December 2020 and held five meetings in 2024. The Board has determined that each member of the Audit Committee is an independent director in accordance with the rules of The Nasdaq Stock Market and applicable federal securities laws and regulations. In addition, the Board has determined that each of Mr. Bernstein and Mr. Schechter is an "audit committee financial expert" within the meaning of Item 407(d)(5) of Regulation S-K and has designated each of them to fill that role. See "— Executive Officers and Directors" above for descriptions of the relevant education and experience of each member of the Audit Committee.

The Audit Committee is responsible for the oversight of the Company's financial reporting process on behalf of the Board and such other matters as specified in the Committee's charter or as directed by the Board. Our Audit Committee is directly responsible for the appointment, compensation, retention and oversight of the work of any registered public accounting firm engaged by us for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for us (or to nominate the independent registered public accounting firm for stockholder approval), and each such registered public accounting firm must report directly to the Audit Committee. Our Audit Committee must approve in advance all audit, review and attest services and all non-audit services (including, in each case, the engagement and terms thereof) to be performed by our independent auditors, in accordance with applicable laws, rules and regulations.

Compensation Committee

The Compensation Committee (i) assists the Board in discharging its responsibilities with respect to compensation of the Company's executive officers and directors, (ii) evaluates the performance of the executive officers of the Company and (iii) administers the Company's stock and incentive compensation plans and recommends changes in such plans to the Board as needed.

The Compensation Committee was established in December 2020 and held three meetings in 2024. The Board has determined that each member of the Compensation Committee is an independent director in accordance with the rules of The Nasdaq Stock Market and applicable federal securities laws and regulations.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee assists the Board in (i) identifying qualified individuals to become directors, (ii) determining the composition of the Board and its committees, (iii) developing succession plans for executive officers, (iv) monitoring a process to assess Board effectiveness, and (v) developing and implementing the Company's corporate governance procedures and policies.

The Nominating and Corporate Governance Committee was established in December 2020 and held one meeting in 2024. The Board has determined that each member of the Nominating and Corporate Governance Committee is an independent director in accordance with the rules of The Nasdaq Stock Market and applicable federal securities laws and regulations.

The Nominating and Corporate Governance Committee considers any timely submitted and qualified director candidates recommended by any security holder entitled to vote in an election of directors. To date no security holders have made any such recommendations.

Pursuant to our by-laws, nominations of persons for election to the Board at an annual meeting or at any special meeting of stockholders for the purpose of electing directors may be made by or at the direction of the Board, by any nominating committee or person appointed for such purpose by the Board, or by any stockholder of record entitled to vote for the election of directors at the meeting who complies with the following notice procedures. Such nominations, other than those made by, or at the direction of, or under the authority of the Board, shall be made pursuant to timely notice in writing to the Secretary of the Company by a stockholder of record

at such time. To be timely, a stockholder's notice must be delivered to or mailed and received at the principal executive offices of the Company (a) in the case of an annual meeting, not less than 90 nor more than 120 days prior to the one-year anniversary of the date of the annual meeting of the previous year; *provided, however*, that if the annual meeting is called for a date that is not within 30 days before or after such anniversary date, notice by the stockholder in order to be timely must be so received no earlier than 120 days prior to such annual meeting and not later than the close of business on the tenth day following the day on which notice of the date of the annual meeting was mailed or public disclosure of the date of the annual meeting was made, whichever first occurs; and (b) in the case of a special meeting of stockholders for the purpose of electing directors, not earlier than 120 days prior to such special meeting and not later than the close of business on the tenth day following the day on which notice of the date of the special meeting was mailed or public disclosure of the date of the special meeting was made, whichever first occurs. Such stockholder's notice to the Secretary must set forth (a) as to each person whom the stockholder proposes to nominate for election or re-election as a director, (i) the name, age, business address and residence address of the person, (ii) the principal occupation or employment of the person, (iii) the class and number of shares of capital stock of the Company, if any, which are beneficially owned by the person and (iv) any other information relating to the person that is required to be disclosed in solicitations for proxies for election of directors pursuant to Regulation 14A under the Exchange Act or other applicable law; and (b) as to the stockholder giving the notice (i) the name and record address of the stockholder and (ii) the class and number of shares of capital stock of the Company which are beneficially owned by the stockholder. The chairman of the meeting may, if the facts warrant, determine and declare to the meeting that a nomination was not made in accordance with the foregoing procedures, and the defective nomination will be disregarded.

Code of Conduct and Ethics

Upon the consummation of the Spin-Off, we adopted a Code of Ethics and Business Conduct ("Code of Ethics") applicable to all of our employees, officers and directors (including our principal executive officer, principal financial officer and principal accounting officer) that complies with SEC regulations.

We intend to timely disclose any amendments to, or waivers from, our Code of Ethics that are required to be publicly disclosed pursuant to rules of the SEC and any securities exchange on which our shares may be listed by filing such amendment or waiver with the SEC.

Involvement in Certain Legal Proceedings

None of our directors or executive officers has been involved in any of the following events during the past ten years:

- any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;
- any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offences);
- being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his or her involvement in any type of business, securities or banking activities; or
- being found by a court of competent jurisdiction (in a civil action), the SEC or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated.

Family Relationships

There are no family relationships among our directors or executive officers.

Item 11. Executive Compensation.

This section describes both the current compensation practices of Synaptogenix as well as the historical compensation practices of Neurotrope.

The following table sets forth information concerning the total compensation paid or accrued by Synaptogenix during the last two fiscal years ended December 31, 2024 to (i) all individuals that served as our principal executive officer or acted in a similar capacity for us at any time during the fiscal year ended December 31, 2024; (ii) the two most highly compensated executive officers other than the principal executive officer who were serving as executive officers at December 31, 2024; and (iii) up to two additional individuals for whom disclosure would have been required pursuant to clause (ii) above but for the fact that the individual was not serving as an executive officer at December 31, 2024 (collectively, the "named executive officers").

The Compensation Committee of the Board is responsible for determining executive compensation.

Summary Compensation Table

Name & Principal Position	Fiscal Year Ended December 31	Salary ($)	Bonus ($)(1)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation	Non-Qualified Deferred Compensation Earnings	All Other Compensation (2)	Total ($)
Dr. Alan J. Tuchman Chief Executive Officer	2024	222,000	50,000	—	—	—	—	6,234	278,234
	2023	222,000	75,000	—	—	—	—	6,347	303,347
Robert Weinstein CFO, Secretary and Executive Vice President	2024	348,408	100,000	—	—	—	—	117,468	565,876
	2023	339,548	150,000	—	—	—	—	79,370	568,918
Daniel L. Alkon MD President and CSO	2024	300,000	50,000	—	—	—	—	—	350,000
	2023	300,000	75,000	—	—	—	—	—	375,000

(1) Mr. Weinstein was paid a $100,000 bonus in 2025 for services rendered during the fiscal year ended 2024. Mr. Weinstein was paid a $150,000 bonus in March 2024 for services rendered during the fiscal year ended 2023. Drs. Tuchman and Alkon were each paid a $50,000 bonus in 2025 for services rendered during the fiscal year ended 2024 and were each paid a $75,000 bonus in 2024 for services rendered during the fiscal year ended 2023.

(2) Mr. Weinstein and Dr. Tuchman's 2023 and 2024 amounts reflect healthcare payments and insurance premiums paid on their behalf.

Executive Employment Arrangements

We have no plans in place and have never maintained any plans that provide for the payment of retirement benefits or benefits that will be paid primarily following retirement including, but not limited to, tax qualified deferred benefit plans, supplemental executive retirement plans, tax-qualified deferred contribution plans and nonqualified deferred contribution plans other than certain cases noted below.

Except as indicated below, we have no contracts, agreements, plans or arrangements, whether written or unwritten, that provide for payments to the named executive officers listed above.

Narrative Disclosure to Summary Compensation Table and Grants of Plan-Based Awards Table

Alan J. Tuchman, M.D. The Company is party to an offer letter (as amended to date, the "Tuchman Agreement") as of December 7, 2020 with Alan J. Tuchman, M.D., pursuant to which Dr. Tuchman serves as Synaptogenix's Chief Executive Officer. Under the terms of the Tuchman Agreement, Dr. Tuchman receives an annual base salary of $222,000, with an annual discretionary bonus of up to 50% of his base salary then in effect. The term of Dr. Tuchman's employment pursuant to the offer letter was initially one year, which was to be extended automatically for six month periods unless either party gave timely written notice. On August 4, 2022, Synaptogenix entered into an amendment to the Tuchman Agreement to extend the term of Dr. Tuchman's employment through June 7, 2023; on June 16, 2023, the Company entered into a second amendment to the Tuchman Agreement to extend the term of Dr. Tuchman's employment

through June 7, 2024; and on June 20, 2024, the Company entered into a third amendment to the Tuchman Agreement to extend the term of Dr. Tuchman's employment through December 7, 2024, with automatic monthly renewals thereafter unless earlier terminated by either party. In November 2024, the Company's Board of Directors amended Dr. Tuchman's base salary to $12,500 per month, effective January 1, 2025. Pursuant to the Tuchman Agreement, if Dr. Tuchman is terminated without cause, Dr. Tuchman shall be entitled to severance equal to six months of Dr. Tuchman's annual base salary, payable in the form of a salary continuation over the six-month period following his termination.

Robert Weinstein. Upon the Spin-Off, Synaptogenix assumed Robert Weinstein's employment agreement with Neurotrope, dated as of October 1, 2013 (the "Weinstein Agreement"), pursuant to which Mr. Weinstein serves as the Synaptogenix's Chief Financial Officer and Executive Vice President. Neurotrope agreed to pay Mr. Weinstein a discretionary annual bonus of up to 50% of his annual base salary for all years beginning January 1, 2015, to be earned and payable based upon attainment of annual performance goals as determined by the Neurotrope board of directors or a committee thereof. Mr. Weinstein was not paid a bonus in 2017 or in 2018. Mr. Weinstein's annual bonus opportunity may be periodically reviewed and increased at the discretion of the Board or a committee thereof. Mr. Weinstein is also eligible to participate in all Synaptogenix benefits generally available to the Synaptogenix's officers in accordance with the terms of those benefit plans and all retirement, life, disability, medical and dental plan benefits generally available to Synaptogenix's officers in accordance with the terms of those plans.

If Mr. Weinstein's employment is terminated by Synaptogenix for a reason other than cause or by him for good reason, and subject to his compliance with other terms of the Weinstein Agreement, and certain other conditions, the Company is required to pay Mr. Weinstein a severance amount equal to Mr. Weinstein's annual base salary, payable in a single lump sum. In addition, if Mr. Weinstein elects health care continuation coverage under COBRA, the Company is obligated to pay for such health insurance coverage for a period of 18 months following the termination of Mr. Weinstein's employment, at the same rate as it pays for health insurance coverage for its active employees (with Mr. Weinstein required to pay for any employee-paid portion of such coverage). If Mr. Weinstein's employment is terminated by non-renewal or due to his death or disability, he will be entitled to any unpaid prorated annual bonus for the year in which his employment terminates. Subject to earlier termination by Mr. Weinstein's death or disability, or by Synaptogenix for cause, the term of Mr. Weinstein's employment agreement is four years and will be extended automatically for successive one-year periods, unless either party gives written notice of termination to the other party at least 90 days prior to the end of the then-current term.

Daniel L. Alkon, M.D. Effective September 23, 2016, Neurotrope appointed Dr. Daniel Alkon, M.D., as President of Neurotrope. Dr. Alkon continues to serve as Synaptogenix's Chief Scientific Officer following the Spin-Off. On January 4, 2017, Neurotrope agreed to compensate Dr. Alkon with compensation of $25,000 per month until May 31, 2017. Since that time, Dr. Alkon has received annual compensation of $300,000. Effective January 1, 2025, Dr. Alkon's compensation was reduced to $16,000 per month.

Pension Benefits

We do not have any qualified or non-qualified defined benefit plans.

Nonqualified Deferred Compensation

We do not have any nonqualified defined contribution plans or other deferred compensation plan.

Potential Payments upon Termination or Change-In-Control

Employment Agreements

Pursuant to the Tuchman Agreement, if Dr. Tuchman is terminated without Cause, Dr. Tuchman shall be entitled to severance equal to six months of Dr. Tuchman's annual base salary, payable in the form of a salary continuation over the six-month period following his termination.

Pursuant to the Weinstein Agreement, if Mr. Weinstein's employment is terminated by the Company for a reason other than cause or by him for good reason, and subject to his compliance with other terms of the Weinstein Agreement and certain other conditions, the Company is obligated to pay him a severance amount equal to his annual base salary, payable in a single lump sum. In addition, if he elects health care continuation coverage under COBRA, the Company will pay for such health insurance coverage for a period of 18

months following the termination of his employment, at the same rate as it pays for health insurance coverage for its active employees (with Mr. Weinstein required to pay for any employee-paid portion of such coverage). If Mr. Weinstein's employment is terminated by non-renewal or due to his death or disability, he will be entitled to any unpaid prorated annual bonus for the year in which his employment terminates.

Equity Plans

Options granted under our 2020 Plan (as defined below) are subject to modification in the event of termination as follows (in each case subject to any modifications made by the plan administrator):

- In case of termination due to death, a participant's vested options may be exercised by their survivors within one year following death.
- In case of termination due to disability, a participant may exercise their vested options within one year of termination.
- In case of termination for Cause (as defined in the 2020 Plan), all of a participant's vested options will be immediately forfeited.
- In case of termination not due to death, disability or Cause, the participant may exercise all vested options for the duration of the term set by the related option agreements (provided that no option intended to be an incentive stock option (ISO) may be exercised later than three months of termination). Further, if the participant becomes disabled or dies within three months of termination, such participant's survivors may exercise the options within one year of termination (but in no event after the expiration date set by the related option agreements).

Stock awards granted under our 2020 Plan are subject to modification in the event of termination as follows (in each case subject to any modifications made by the plan administrator):

- In case of termination due to death, a participant's vested stock awards may be exercised by their survivors subject to their terms.
- In case of termination due to disability, a participant may exercise their vested stock awards subject to their terms.
- In case of termination for Cause (as defined in the 2020 Plan), all of a participant's vested stock awards that remain subject to forfeiture or repurchase provisions will be immediately forfeited.
- In case of termination not due to death, disability or Cause, the Company shall have the right to cancel or repurchase shares subject to stock awards held by the participant that remain subject to forfeiture or repurchase provisions.

Pursuant to the 2020 Plan, in the event of a Change of Control that is also a Corporate Transaction (as each term is defined in the 2020 Plan), all outstanding options on such date shall become automatically fully vested. Additionally, the Board has the right to determine any adjustments to outstanding awards following a Change of Control.

2020 Equity Incentive Plan

In connection with the Spin-Off, the Company adopted the 2020 Equity Incentive Plan (the "2020 Plan") in November 2020. The purpose of the 2020 Plan is to allow non-employee directors and selected employees, officers and consultants ("Grantees") to acquire equity ownership in the Company, thereby strengthening their commitment to the Company's success and incentivizing their efforts on behalf of the Company. The 2020 Plan is also intended to assist the Company in attracting new employees and Board members and retaining existing ones. Finally, the 2020 Plan supports and increases our ability to facilitate the sustained progress, growth and profitability of the Company.

On April 7, 2021, the Company's stockholders approved an amendment to the 2020 Plan to increase the total number of shares of Common Stock from 10,000 to an aggregate of 55,000 shares of Common Stock, and on October 11, 2022, the Company's stockholders approved an amendment to the 2020 Plan to increase the total number of shares of Common Stock from 55,000 to an aggregate of 175,000 shares of Common Stock.

The Compensation Committee of our Board (the "Committee") administers the 2020 Plan and has full power to grant stock options and Common Stock, construe and interpret the 2020 Plan, establish rules and regulations and perform all other acts, including the delegation of administrative responsibilities, as it believes reasonable and proper. Any decision made or action taken by the Committee arising out of or in connection with the interpretation and administration of the 2020 Plan will be final and conclusive. The Committee, in its absolute discretion, may award Common Stock to employees, consultants, and directors of the Company, and such other persons as the Committee may select, and permit holders of options to exercise such options prior to full vesting.

In the event that our outstanding Common Stock is changed into or exchanged for a different number or kind of shares or other securities of the Company by reason of merger, consolidation, other reorganization, recapitalization, combination of shares, stock split-up or stock dividend, equitable adjustment will be made to the aggregate number and kind of shares subject to stock options which may be granted under the 2020 Plan.

The Committee may at any time, and from time to time, suspend or terminate the 2020 Plan in whole or in part or amend it from time to time in such respects as it may deem appropriate and in our best interest.

Outstanding Equity Awards at 2024 Fiscal Year-End

The following table shows grants of stock options and grants of unvested stock awards outstanding on the last day of the fiscal year ended December 31, 2024, including both awards subject to performance conditions and non-performance-based awards, to each of the executive officers named in the Summary Compensation Table.

	Option Awards				
Name T (a)	Number Of Securities Underlying Unexercised Options (#) Exercisable (b)	Number of Securities Underlying Unexercised Options (#) Unexercisable (c)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#) (d)	Option Exercise Price ($) (e)	Option Expiration Date (f)
Dr. Alan J. Tuchman					
Chief Executive Officer	503	— (1)	—	$ 246.00	01/13/2031
	246	— (2)	—	$ 182.25	02/16/2032
	2,754	— (3)	—	$ 151.75	11/15/2032
Robert Weinstein CFO, Secretary and Executive Vice President	445	— (1)	—	$ 246.00	1/13/2031
	3,000	— (3)	—	$ 151.75	11/15/2032
Daniel L. Alkon MD President and CSO	1,250	— (1)	—	$ 246.00	01/13/2031
	3,000	— (3)	—	$ 151.75	11/15/2032

(1) The options vested in full on January 13, 2021.

(2) The options vested in full on February 16, 2023.

(3) The options vested in full on May 15, 2023.

Director Compensation

Synaptogenix reimburses its directors for all reasonable out-of-pocket expenses incurred in connection with their attendance at meetings of the Board. On March 29, 2023, Synaptogenix adopted a new non-employee director compensation policy (the “Director Compensation Policy”). The Director Compensation Policy provides for the annual automatic grant of nonqualified stock options to purchase up to 800 shares of Synaptogenix’s Common Stock to each of Synaptogenix’s non-employee directors. Such grants shall occur annually on the fifth business day after the filing of Synaptogenix’s Annual Report on Form 10-K and shall vest on the one-year anniversary from the date of grant subject to the director’s continued service on the Board on the vesting date. The Director Compensation Policy also provides for the automatic grant of nonqualified stock options to purchase up to 800 shares of Synaptogenix’s Common Stock to each newly appointed director following the date of his or her appointment. Such options shall vest as follows: fifty percent (50%) on the date of the grant, twenty-five percent (25%) on the one-year anniversary from the date of the grant, and twenty-five percent (25%) on the second-year anniversary from the date of the grant, subject to the director’s continued service on the Board

on the applicable vesting dates. Each non-employee director will also receive an annual retainer: $120,000 for the Chairman of the Board, $100,000 for the Vice Chairman of the Board and $60,000 for each other non-employee board member.

The following table provides information concerning the compensation of Synaptogenix's directors for the year ended December 31, 2024.

Name	Fees earned or paid in cash ($)	Stock awards ($)	Option awards ($)(1)	Non-equity incentive plan compensation ($)	Non-qualified deferred compensation earnings ($)	All other Compensation ($)	Total ($)
Joshua Silverman (2)	340,000	—	3,760	—	—	—	343,760
William S. Singer (3)	150,000	—	3,760	—	—	—	153,760
Alan J. Tuchman (4)	—	—	—	—	—	—	—
Daniel Alkon (5)	—	—	—	—	—	—	—
Bruce T. Bernstein (6)	110,000	—	3,760	—	—	—	113,760
Jonathan L. Schechter(7)	110,000	—	3,760	—	—	—	113,760

(1) These amounts represent the aggregate grant date fair value of options granted to each director in 2025 for services performed in 2024 computed in accordance with FASB ASC Topic 718.

(2) Fees represent payments for consulting services provided by Mr. Silverman and compensation for his position as Chairman of the Board. Mr. Silverman had 5,910 option awards outstanding at December 31, 2024.

(3) Mr. Singer had 5,010 option awards outstanding at December 31, 2024.

(4) Dr. Tuchman's compensation for 2024 is disclosed above in the Summary Compensation table.

(5) Dr. Alkon's compensation for 2024 is disclosed above in the Summary Compensation table.

(6) Mr. Bernstein had 5,000 option awards outstanding at December 31, 2024.

(7) Mr. Schechter had 4,793 option awards outstanding at December 31, 2024.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters.

Security Ownership of Certain Beneficial Owners

The following table sets forth information with respect to the beneficial ownership of our Common Stock as of March 25, 2025, by (i) each stockholder known by us to be the beneficial owner of more than 5% of our Common Stock (our only class of voting securities), (ii) each of our directors and executive officers, and (iii) all of our directors and executive officers as a group. To the best of our knowledge, except as otherwise indicated, each of the persons named in the table has sole voting and investment power with respect to the shares of our Common Stock beneficially owned by such person, except to the extent such power may be shared with a spouse. To our knowledge, none of the shares listed below are held under a voting trust or similar agreement, except as noted.

Name and Address of Beneficial Owner(1)	Common Stock Beneficially Owned	Percent of Common Stock Beneficially Owned(2)
More than 5% stockholders:		
N/A		
Directors and Named Executive Officers:		
Daniel L. Alkon(3)	5,672	* %
Bruce T. Bernstein(4)	6,103	* %
Jonathan Schechter(5)	5,883	* %
Joshua N. Silverman(6)	7,440	* %
William S. Singer(7)	6,330	* %
Alan J. Tuchman(8)	4,823	* %
Robert Weinstein(9)	4,776	* %
All current directors and executive officers as a group (7 persons)	41,026	2.89 %

* Represents beneficial ownership of less than 1% of the outstanding shares.

(1) Unless otherwise indicated, the business address for each stockholder listed is c/o Synaptogenix, Inc., 1185 Avenue of the Americas, 3rd Floor, New York, NY 10036.

(2) Applicable percentage ownership is based on 1,389,815 shares of our Common Stock outstanding, together with securities exercisable or convertible into shares of our Common Stock within 60 days of March 25, 2025 for each stockholder. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. The shares issuable pursuant to the exercise or conversion of such securities are deemed outstanding for the purpose of computing the percentage of ownership of the security holder, but are not treated as outstanding for the purpose of computing the percentage of ownership of any other person.

(3) Consists of 1,422 shares of Common Stock and options to purchase 4,250 shares of Common Stock that are exercisable within 60 days of March 25, 2025.

(4) Consists of 1,103 shares of Common Stock and options to purchase 5,000 shares of Common Stock that are exercisable within 60 days of March 25, 2025.

(5) Consists of 1,090 shares of Common Stock and options to purchase 4,793 shares of Common Stock that are exercisable within 60 days of March 25, 2025.

(6) Consists of 1,530 shares of Common Stock and options to purchase 5,910 shares of Common Stock that are exercisable within 60 days of March 25, 2025.

(7) Consists of 1,320 shares of Common Stock and options to purchase 5,010 shares of Common Stock that are exercisable within 60 days of March 25, 2025.

(8) Consists of 1,320 shares of Common Stock and options to purchase 3,503 shares of Common Stock that are exercisable within 60 days of March 25, 2025.

(9) Consists of 1,328 shares of Common Stock, warrants to purchase 3 shares of Common Stock that are exercisable within 60 days of March 25, 2025 and options to purchase 3,445 shares of Common Stock that are exercisable within 60 days of March 25, 2025.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

SEC rules require us to disclose any transaction or currently proposed transaction in which we are a participant and in which any related person has or will have a direct or indirect material interest involving an amount that exceeds the lesser of $120,000 or one percent (1%) of the average of the Company's total assets as of the end of last two completed fiscal years. A related person is any executive officer, director, nominee for director, or holder of 5% or more of the Company's Common Stock, or an immediate family member of any of those persons.

On August 4, 2016, Neurotrope entered into a consulting agreement with SM Capital Management, LLC ("SMCM"), a limited liability company owned and controlled by the Company's Chairman of the Board, Mr. Joshua N. Silverman (the "Consulting Agreement"). Pursuant to the Consulting Agreement, SMCM shall provide consulting services which shall include, but not be limited to, providing business development, financial communications and management transition services, for a one-year period, subject to annual review thereafter. SMCM's annual consulting fee is $120,000, payable by the Company in monthly installments of $10,000. In addition, SMCM shall be reimbursed for (i) all pre-approved travel in connection with the consulting services to the Company, (ii) upon submission to the Company of appropriate vouchers and receipts, for all other out-of-pocket expenses reasonably incurred by SMCM in furtherance of the Company's business. This contract was assigned to Synaptogenix on December 1, 2020.

We believe that the transactions and agreements discussed below (including renewals of any existing agreements) between us and related third parties are at least as favorable to us as could have been obtained from unrelated parties at the time they were entered into.

Policy and Procedures Governing Related Person Transactions

Our Audit Committee of the Board utilizes procedures in evaluating the terms and provisions of proposed related party transactions or agreements in accordance with the fiduciary duties of directors under Delaware law. Our related party transaction procedures contemplate Audit Committee review and approval of all new agreements, transactions or courses of dealing with related parties, including any modifications, waivers or amendments to existing related party transactions. We will test to ensure that the terms of related party transactions are at least as favorable to us as could have been obtained from unrelated parties at the time of the transaction. The Audit Committee will consider, at a minimum, the nature of the relationship between us and the related party, the history of the transaction (in the case of modifications, waivers or amendments), the terms of the proposed transaction, our rationale for entering into the transaction and the terms of comparable transactions with unrelated third parties. In addition, management and internal audit will annually analyze all existing related party agreements and transactions and review them with the Audit Committee.

Director Independence

See "Item 10. Directors, Executive Officers and Corporate Governance—Director Independence" and "Item 10. Directors, Executive Officers and Corporate Governance—Board Committees" above.

Item 14. Principal Accountant Fees and Services.

The Company engaged Morison Cogen LLP ("Morison") as its independent auditors from August 16, 2022 to September 30, 2024. Morison resigned from its role as the Company's independent registered public accounting firm on September 30, 2024, in conjunction with its exit from providing audit services to publicly traded companies. During the fiscal years ended December 31, 2023 and December 31, 2022 and the subsequent interim period through September 30, 2024, (i) there were no disagreements within the meaning of Item 304(a)(1)(iv) of Regulation S-K, between the Company and Morison on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, any of which that, if not resolved to Morison's satisfaction, would have caused Morison to make reference to the subject matter of any such disagreement in connection with its reports for such years and interim period, and (ii) there were no reportable events within the meaning of Item 304(a)(1)(v) of Regulation S-K.

In October 2024, the Company engaged Stephano Slack LLC ("Stephano Slack") as its independent registered public accounting firm. The following table presents fees for professional audit services rendered by Morison for the review of the Company's interim financial statements for the interim quarterly periods ended March 31, June 30 and September 30, 2023 and the Company's annual financial statements for the year ended December 31, 2023, as well as consent-related fees and fees for professional services rendered by Morison for their audit of the Company's December 31, 2023 financial statements and review of the Company's interim financial statements for the periods ended March 31, June 30 and September 30, 2024. Fees attributed to the year ended December 31, 2024 consisted of payments to both Morison and Stephano Slack of $145,007 and $33,596, respectively.

	2024	2023
Audit fees:	$ 178,603	$ 188,829
Audit related fees:	—	—
Tax fees:	—	—
All other fees:	—	—
Total	$ 178,603	$ 188,829

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Public Accountant

Consistent with SEC policies regarding auditor independence, the Audit Committee has responsibility for appointing, setting compensation and overseeing the work of our independent registered public accounting firm. In recognition of this responsibility, the Audit Committee has established a policy to pre-approve all audit and permissible non-audit services provided by our independent registered public accounting firm.

Prior to engagement of an independent registered public accounting firm for the next year's audit, management will submit an aggregate of services expected to be rendered during that year for each of four categories of services to the Audit Committee for approval.

1. Audit services include audit work performed in the preparation of financial statements, as well as work that generally only an independent registered public accounting firm can reasonably be expected to provide, including comfort letters, statutory audits, and attest services and consultation regarding financial accounting and/or reporting standards.

2. Audit-Related services are for assurance and related services that are traditionally performed by an independent registered public accounting firm, including due diligence related to mergers and acquisitions, employee benefit plan audits, and special procedures required to meet certain regulatory requirements.

3. Tax services include all services performed by an independent registered public accounting firm's tax personnel except those services specifically related to the audit of the financial statements, and includes fees in the areas of tax compliance, tax planning, and tax advice.

4. Other Fees are those associated with services not captured in the other categories. The Company generally does not request such services from our independent registered public accounting firm.

Prior to engagement, the Audit Committee pre-approves these services by category of service. The fees are budgeted and the Audit Committee requires our independent registered public accounting firm and management to report actual fees versus the budget periodically throughout the year by category of service. During the year, circumstances may arise when it may become necessary to engage our independent registered public accounting firm for additional services not contemplated in the original pre-approval. In those instances, the Audit Committee requires specific pre-approval before engaging our independent registered public accounting firm.

The Audit Committee may delegate pre-approval authority to one or more of its members. The member to whom such authority is delegated must report, for informational purposes only, any pre-approval decisions to the Audit Committee at its next scheduled meeting.

PART IV

Item 15. Exhibits and Financial Statements Schedules.

The following documents are filed as part of this Annual Report on Form 10-K:

(a)(1) and (2) See "Index to Financial Statements and Financial Statement Schedules" at Item 8 to this Annual Report on Form 10-K. Other financial statement schedules have not been included because they are not applicable or the information is included in the financial statements or notes thereto.

(a)(3) Exhibits

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Number	
3.1	Amended and Restated Certificate of Incorporation of Synaptogenix, Inc., dated as of December 7, 2020 (incorporated by reference from Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on December 10, 2020)
3.2	Bylaws of Synaptogenix, Inc. (incorporated by reference from Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed with the SEC on December 10, 2020)
3.3	Amendment to the Bylaws of Synaptogenix, Inc. (incorporated by reference from Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on December 28, 2022)
3.4	Certificate Of Designations of Series B Convertible Preferred Stock of Synaptogenix, Inc. (incorporated by reference from Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on November 22, 2022)
3.5	First Amendment to Certificate Of Designations of Series B Convertible Preferred Stock of Synaptogenix, Inc. (incorporated by reference from Exhibit 3.5 to the Registrant's Annual Report on Form 10-K filed on March 21, 2023)
3.6	Second Amendment to Certificate Of Designations of Series B Convertible Preferred Stock of Synaptogenix, Inc. (incorporated by reference from Exhibit 3.2 to the Registrant's Quarterly Report on Form 10-Q filed on May 15, 2023)
3.7	Third Amendment to Certificate of Designations of Series B Convertible Preferred Stock of Synaptogenix, Inc. (incorporated by reference from Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on September 9, 2024)
3.8	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Synaptogenix, Inc. (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on April 4, 2024)
3.9	Certificate Of Designations of Series C Convertible Preferred Stock of Synaptogenix, Inc. (incorporated by reference from Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on September 13, 2024)
4.1	Form of Series A Common Stock Warrant (incorporated by reference from Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, filed with the SEC)
4.2	Form of Series B Common Stock Warrant (incorporated by reference from Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, filed with the SEC on October 9, 2020)
4.3	Form of Series C Common Stock Warrant (incorporated by reference from Exhibit 4.3 to the Registrant's Registration Statement on Form S-1, filed with the SEC on October 9, 2020)

4.4	Form of Series D Common Stock Warrant (incorporated by reference from Exhibit 4.4 to the Registrant's Registration Statement on Form S-1, filed with the SEC on October 9, 2020)
4.6	Form of Series F Warrant (incorporated by reference from Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 22, 2021)
4.7	Form of Series G Warrant (incorporated by reference from Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on June 16, 2021)
4.8	Form of Pre-Funded Warrant (incorporated by reference from Exhibit 4.3 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 22, 2021)
4.9	Form of Pre-Funded Warrant (incorporated by reference from Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on June 16, 2021)
4.10	Form of Broker Warrant (incorporated by reference from Exhibit 4.4 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 22, 2021)
4.11	Form of Broker Warrant (incorporated by reference from Exhibit 4.3 to the Registrant's Current Report on Form 8-K, filed with the SEC on June 16, 2021)
4.12	Form of Warrant (incorporated by reference from Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on November 18, 2022)
4.13	Form of Warrant (incorporated by reference from Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on September 11, 2024)
10.1**	Separation and Distribution Agreement, dated as of December 6, 2020, by and between Neurotrope, Inc. and Synaptogenix, Inc. (incorporated by reference from Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on December 10, 2020)
10.2	Tax Matter Agreement, dated as of December 6, 2020, by and between Neurotrope, Inc. and Synaptogenix, Inc. (incorporated by reference from Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on December 10, 2020)
10.3†	Offer Letter, dated as of December 7, 2020, by and between Alan J. Tuchman, Ph.D. and Synaptogenix, Inc. (incorporated by reference from Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed with the SEC on December 10, 2020)
10.4†	First Amendment to Offer Letter, dated as of August 4, 2022, by and between Alan J. Tuchman, Ph.D. and Synaptogenix, Inc. (incorporated by reference from Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 5, 2022)
10.5†	Second Amendment to Offer Letter, dated as of June 16, 2023, by and between Alan J. Tuchman, Ph.D. and Synaptogenix, Inc. (incorporated by reference from Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on June 22, 2023)
10.6†	Third Amendment to Offer Letter, dated as of June 20, 2024, by and between Alan J. Tuchman, M.D. and Synaptogenix, Inc. (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed with the SEC on November 12, 2024)
10.7†	Fourth Amendment to Offer Letter, dated as of December 16, 2024, by and between Alan J. Tuchman, M.D. and Synaptogenix, Inc. (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on December 16, 2024)

10.8†	2020 Equity Incentive Plan of Synaptogenix, Inc. (incorporated by reference from Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed with the SEC on December 10, 2020)
10.9†	First Amendment to the Synaptogenix, Inc. 2020 Equity Incentive Plan (incorporated by reference from Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 8, 2021)
10.10†	Second Amendment to the Synaptogenix, Inc. 2020 Equity Incentive Plan (incorporated by reference from Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on October 13, 2022)
10.11†	Form of Stock Option Agreement under 2020 Equity Incentive Plan of Synaptogenix, Inc. (incorporated by reference from Exhibit 10.6 to the Registrant's Current Report on Form 8-K filed with the SEC on December 10, 2020)
10.12†	Employment Agreement, dated as of October 1, 2013, between Neurotrope, Inc. and Robert Weinstein (assumed by Synaptogenix, Inc. on December 7, 2020) (incorporated by reference to Exhibit 10.7 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the SEC on March 30, 2021)
10.13†	Non - employee Director Compensation Policy (incorporated by reference from Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on May 15, 2023)
10.14†	Form of Director Indemnification Agreement (incorporated by reference to Exhibit 10.9 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the SEC on March 30, 2021)
10.15	Amended and Restated Technology License and Services Agreement among Neurotrope BioScience, Inc., Blanchette Rockefeller Neurosciences Institute and NRV II, LLC, made as of February 4, 2015 (incorporated by reference to Exhibit 10.10 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the SEC on March 30, 2021)
10.16	Amendment to Amended and Restated Technology License and Services Agreement among Neurotrope BioScience, Inc., Blanchette Rockefeller Neurosciences Institute and NRV II, LLC, dated November 12, 2015 (incorporated by reference to Exhibit 10.13 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the SEC on March 30, 2021)
10.17	Second Amendment to the Amended and Restated Technology License by and between Neurotrope BioScience, Inc. and Cognitive Research Enterprises, Inc., dated November 29, 2018 (incorporated by reference to Exhibit 10.17 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the SEC on March 30, 2021)
10.18†	Services Agreement between Neurotrope BioScience, Inc. and Worldwide Clinical Trials, Inc., dated October 9, 2015 (incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the SEC on March 30, 2021)
10.19†	Services Agreement by and between Neurotrope, Inc. and Worldwide Clinical Trials, Inc., dated as of May 4, 2018 (assumed by Synaptogenix, Inc. on December 7, 2020) (incorporated by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the SEC on March 30, 2021)
10.20	Securities Purchase Agreement, dated January 21, 2021, by and among Synaptogenix, Inc. and the Buyers signatory thereto (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, filed on January 22, 2021)
10.21	Securities Purchase Agreement, dated June 14, 2021, by and among Synaptogenix, Inc. and the Buyers signatory thereto (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, filed on June 16, 2021)

10.22	Securities Purchase Agreement, dated November 17, 2022, by and among Synaptogenix, Inc. and the investors named therein (incorporated by reference from Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on November 18, 2022)
10.23	Securities Purchase Agreement, dated as of September 10, 2024, by and among Synaptogenix, Inc. and the investors named therein (incorporated by reference from Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on September 10, 2024)
10.24	Registration Rights Agreement, dated January 21, 2021, by and among Synaptogenix, Inc. and the Buyers signatory thereto (incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K, filed on January 22, 2021)
10.25	Registration Rights Agreement, dated June 14, 2021, by and among Synaptogenix, Inc. and the Buyers signatory thereto (incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K, filed on June 16, 2021)
10.26	Registration Rights Agreement, dated November 17, 2022, by and among Synaptogenix, Inc. and the buyers named therein (incorporated by reference from Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on November 18, 2022)
10.27	Registration Rights Agreement, dated as of September 10, 2024, by and among Synaptogenix, Inc. and the investors named therein (incorporated by reference from Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on September 11, 2024)
10.28	Engagement Letter, dated January 20, 2021, by and between Synaptogenix, Inc. and Katalyst Securities LLC (incorporated by reference to Exhibit 10.3 to our Current Report on Form 8-K, filed on January 22, 2021)
10.29	Engagement Letter, dated June 14, 2021, by and between Synaptogenix, Inc. and Katalyst Securities LLC (incorporated by reference to Exhibit 10.3 to our Current Report on Form 8-K, filed on June 16, 2021)
10.30	Engagement Letter, dated November 17, 2022, by and between Synaptogenix, Inc. and Katalyst Securities LLC (incorporated by reference to Exhibit 10.3 to our Current Report on Form 8-K, filed on November 18, 2022)
10.31	Engagement Letter, dated September 10, 2024, by and between Synaptogenix, Inc. and GP Nurmenkari Inc. (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the SEC on September 11, 2024)
10.32	Placement Agency Agreement, dated January 21, 2021, by and between Synaptogenix, Inc., and GP Nurmenkari Inc. (incorporated by reference to Exhibit 10.4 to our Current Report on Form 8-K, filed on January 22, 2021)
10.33	Consulting Agreement, dated December 16, 2024, by and between the Company and Dr. Daniel L. Alkon, M.D. (incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K, filed on December 20, 2024)
19.1	Synaptogenix, Inc. Insider Trading Policy (incorporated by reference from Exhibit 19.1 to the Registrant's Annual Report on Form 10-K filed with the SEC on April 1, 2024)
21.1	Subsidiaries of the Company (incorporated by reference from Exhibit 21.1 to the Registrant's Registration Statement on Form S-1 filed with the SEC on February 8, 2021)
23.1*	Consent of Morison Cogen LLP
23.2*	Consent of Stephano Slack LLC
31.1*	Rule 13(a)-14(a)/15(d)-14(a) Certification of Principal Executive Officer
31.2*	Rule 13(a)-14(a)/15(d)-14(a) Certification of Principal Financial and Accounting Officer

32.1*	Section 1350 Certification of Principal Executive Officer and Principal Financial Officer (This certification is being furnished and shall not be deemed "filed" with the SEC for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.)
97.1	Synaptogenix, Inc. Clawback Policy (incorporated by reference from Exhibit 97.1 to the Registrant's Annual Report on Form 10-K filed with the SEC on April 1, 2024)
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit)

* Filed herewith.

** Schedules and exhibits omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant will furnish a copy of any omitted schedule or exhibit as a supplement to the SEC or its staff upon request.

† Management contract or compensatory plan or arrangement.

+ Certain confidential portions of this Exhibit were omitted because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURE

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, thereunto duly authorized in the City of New York, New York, on March 27, 2025.

SYNAPTOGENIX, INC.
By: /s/ Alan J. Tuchman, M.D.
Name: Alan J. Tuchman, M.D.
Title: Chief Executive Officer
(principal executive officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Alan J. Tuchman, M.D. and Robert Weinstein (with full power to act alone), as his true and lawful attorneys-in-fact and agents, with full powers of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitute or substitutes, lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Alan J. Tuchman, M.D. Alan J. Tuchman, M.D.	Chief Executive Officer and Director (Principal Executive Officer)	March 27, 2025
/s/ Robert Weinstein Robert Weinstein	Chief Financial Officer (Principal Financial and Principal Accounting Officer)	March 27, 2025
/s/ Joshua N. Silverman Joshua N. Silverman	Director and Chairman of the Board	March 27, 2025
/s/ William S. Singer William S. Singer	Director and Vice-Chairman of the Board	March 27, 2025
/s/ Bruce T. Bernstein Bruce T. Bernstein	Director	March 27, 2025
/s/ Jonathan L. Schechter Jonathan L. Schechter	Director	March 27, 2025
/s/ Daniel Alkon, M.D. Daniel Alkon, M.D.	Director	March 27, 2025

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Synaptogenix, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheet of Synaptogenix, Inc. (the Company) as of December 31, 2024 and the related statements of comprehensive loss, stockholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audit 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 free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ Stephano Slack LLC (PCAOB ID#03523)

We have served as the Company's auditor since 2024.

Wayne, Pennsylvania
March 27, 2025

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Synaptogenix, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheet of Synaptogenix, Inc. (the Company) as of December 31, 2023 and the related statements of comprehensive loss, stockholders' equity, and cash flows for the year ended December 31, 2023, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023, and the results of its operations and its cash flows for the year ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audit 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 free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ Morison Cogen LLP (00536)

We served as the Company's auditor from 2022 to 2024.

Blue Bell, Pennsylvania
April 1, 2024

SYNAPTOGENIX, INC.

BALANCE SHEETS

	December 31, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 17,656,221	$ 28,661,498
Prepaid Clinical trial expenses	—	375,085
Available for sale debt security	—	1,438,500
Prepaid expenses and other current assets	64,633	57,677
TOTAL CURRENT ASSETS	17,720,854	30,532,760
Equity method investment	—	562,402
Fixed assets, net of accumulated depreciation	12,925	18,505
TOTAL ASSETS	$ 17,733,779	$ 31,113,667
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 317,287	$ 444,633
Accrued expenses	696,980	435,891
Accrued Convertible Preferred payments payable	—	3,395,945
TOTAL CURRENT LIABILITIES	1,014,267	4,276,469
Warrant liability	3,766,000	140,000
Derivative liability	6,177,000	1,113,000
TOTAL LIABILITIES	10,957,267	5,529,469
Commitments and contingencies		
Series B Convertible redeemable preferred stock, $.0001 par value and $1,000 face value, 1,000,000 shares authorized; 0 and 6,000 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively. Liquidation preference of $0 plus dividends accrued at 7% per annum of $0 as of December 31, 2024.	—	1,236,940
Series C Convertible redeemable preferred stock, $.0001 par value and $1,000 face value, 1,000,000 shares authorized; 4,285 and 0 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively. Liquidation preference of $4,285,000 plus dividends accrued at 5% per annum of $35,708 as of December 31, 2024.	912,830	—
STOCKHOLDERS' EQUITY		
Common stock - 150,000,000 shares authorized, $0.0001 par value; 1,357,165 shares issued and outstanding as of December 31, 2024 and 963,489 shares issued and outstanding as of December 31, 2023.*	137	96
Additional paid-in capital	53,027,049	57,957,008
Accumulated other comprehensive income	5,702	902
Accumulated deficit	(47,169,206)	(33,610,748)
TOTAL STOCKHOLDERS' EQUITY	5,863,682	24,347,258
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 17,733,779	$ 31,113,667

The accompanying notes are an integral part of these financial statements.

SYNAPTOGENIX, INC.

STATEMENTS OF COMPREHENSIVE LOSS

	Year Ended December 31, 2024	Year Ended December 31, 2023
OPERATING EXPENSES:		
Research and development	$ 1,598,722	$ 1,974,924
General and administrative	5,212,010	6,338,930
TOTAL OPERATING EXPENSES	6,810,732	8,313,854
OTHER INCOME (LOSS):		
Interest income	1,275,885	1,648,950
Share of net loss in equity investment	(44,525)	—
Loss on write-off of available for debt security	(2,443,300)	—
Loss on write-off of equity investment	(517,877)	—
Warrant issuance cost	(618,375)	—
Loss on issuance of Series C Preferred Stock	(3,812,625)	—
Change in fair value of warrant liability	(829,000)	1,370,000
Change in fair value of derivative liability	1,032,000	(743,600)
TOTAL OTHER INCOME (LOSS)	(5,957,817)	2,275,350
Net loss (income) before income taxes	12,768,549	6,038,504
Provision for income taxes	—	—
Net loss	12,768,549	6,038,504
Preferred Stock dividends	789,909	2,047,774
Deemed dividend-preferred stock extinguishment	—	5,693,000
Net Loss attributable to common stockholders	$ 13,558,458	$ 13,779,278
Change in fair value of available for sale debt security	4,800	(902)
Net comprehensive loss	$ 13,553,658	$ 13,778,376
PER SHARE DATA:		
Basic and diluted loss per common share *	$ 10.99	$ 29.56
Basic and diluted weighted average common shares outstanding *	1,233,700	466,100

The accompanying notes are an integral part of these financial statements.

SYNAPTOGENIX, INC.

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	Year Ended December 31, 2023									
	Series B Preferred Stock		Series C Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance January 1, 2023	15,000	$ 2,721,723	—	$ —	290,485	$ 29	$ 52,524,461	$ (19,831,517)	$ —	$ 32,692,973
Stock based compensation	—	—	—	—	—	—	1,009,325	—	—	1,009,325
Issuance of common stock for consulting fees	—	—	—	—	5,096	1	117,999	—	—	118,000
Accrued preferred stock dividends	—	—	—	—	—	—	—	—	—	—
Preferred stock dividends paid	—	1,022,149	—	—	—	—	—	(1,022,149)	—	(1,022,149)
Reclassification of accrued dividends upon probable redemption of preferred stock	—	165,375	—	—	—	—	—	—	—	—
Deemed dividends on preferred stock	—	140,374	—	—	81,901	8	815,363	(1,025,578)	—	(210,207)
Deemed dividend - preferred stock extinguishment	—	—	—	—	—	—	5,693,000	(5,693,000)	—	—
Preferred stock redemptions and conversions	(6,000)	(6,783,704)	—	—	585,907	58	5,163,828	—	—	5,163,886
Accrual of preferred stock and dividend redemption	(3,000)	(3,395,945)	—	—	—	—	—	—	—	—
Preferred stock accretion	—	7,366,968	—	—	—	—	(7,366,968)	—	—	(7,366,968)
Change in fair value of convertible note receivable - investment in debt security	—	—	—	—	—	—	—	—	902	902
Net loss	—	—	—	—	—	—	—	(6,038,504)	—	(6,038,504)
Balance December 31, 2023	6,000	$ 1,236,940	—	$ —	963,389	$ 96	$ 57,957,008	$ (33,610,748)	$ 902	$ 24,347,258

	Year Ended December 31, 2024									
	Series B Preferred Stock		Series C Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance January 1, 2024	6,000	$ 1,236,940	—	$ —	963,389	$ 96	$ 57,957,008	$ (33,610,748)	$ 902	$ 24,347,258
Stock based compensation	—	—	—	—	—	—	25,407	—	—	25,407
Issuance of preferred stock	—	—	5,000	—	—	—	—	—	—	—
Issuance of common stock for consulting fees	—	—	—	—	19,557	3	117,998	—	—	118,001
Preferred stock dividends	—	396,640	—	69,736	—	—	—	(466,376)	—	(466,376)
Deemed dividends on preferred stock	—	271,086	—	52,447	—	—	—	(323,533)	—	(323,533)
Preferred stock redemptions and conversions	(6,000)	(6,815,978)	(715)	(801,694)	374,219	38	1,430,289	—	—	1,430,327
Accrual of preferred stock and dividend redemption	—	—	—	—	—	—	—	—	—	—
Preferred stock accretion	—	4,911,312	—	1,592,341	—	—	(6,503,653)	—	—	(6,503,653)
Comprehensive income (loss)	—	—	—	—	—	—	—	—	4,800	4,800
Net loss	—	—	—	—	—	—	—	(12,768,549)	—	(12,768,549)
Balance December 31, 2024	—	$ —	4,285	$ 912,830	1,357,165	$ 137	$ 53,027,049	$ (47,169,206)	$ 5,702	$ 5,863,682

The accompanying notes are an integral part of these financial statements.

SYNAPTOGENIX, INC.

STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2024	Year Ended December 31, 2023
CASH FLOW USED IN OPERATING ACTIVITIES		
Net loss	$ (12,768,549)	$ (6,038,504)
Adjustments to reconcile net loss to net cash used by operating activities		
Stock based compensation	25,407	1,009,325
Warrant issuance cost	618,375	—
Loss on issuance of Series C Converetible Preferred Stock	3,812,625	—
Change in fair value of warrant liability	829,000	(1,370,000)
Change in fair value of derivative liability	(1,032,000)	743,600
Share of net loss in equity investment	44,525	—
Loss on write-off of available for debt security	2,443,300	—
Loss on write-off of equity investment	517,877	—
Consulting services paid by issuance of common stock	118,001	118,000
Depreciation expense	5,580	6,347
Change in assets and liabilities:		
Decrease in prepaid expenses and other current assets	368,128	674,419
Decrease in accounts payable	(127,346)	(215,573)
Increase (decrease) in accrued expenses	261,089	(100,823)
	7,884,561	865,295
Net Cash Used in Operating Activities	(4,883,988)	(5,173,209)
CASH FLOWS USED IN INVESTING ACTIVITIES		
Purchase of equity method investment	—	(562,402)
Purchase of available for sale debt security	(1,000,000)	(1,437,598)
Purchase of fixed assets	—	(2,707)
Net Cash Used in Investing Activities	(1,000,000)	(2,002,707)
CASH FLOWS FROM FINANCING ACTIVITIES		
Net proceeds from issuance of Series C Convertible Preferred Stock	4,463,000	—
Redemption of Series B Convertible Preferred Stock	(7,831,677)	(1,000,000)
Redemption of Series C Convertible Preferred Stock	(801,694)	—
Dividends on Series B Convertible Preferred Stock	(950,918)	(641,066)
Net Cash Used in Financing Activities	(5,121,289)	(1,641,066)
NET DECREASE IN CASH AND EQUIVALENTS	(11,005,277)	(8,816,982)
CASH AND EQUIVALENTS AT BEGINNING OF YEAR	28,661,498	37,478,480
CASH AND EQUIVALENTS AT END OF YEAR	$ 17,656,221	$ 28,661,498
DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Issuance of Common Stock for Series B Convertible Preferred Stock installment conversions	$ 1,430,327	$ 5,979,257
Accretion of Series B Convertible Preferred Stock to redemption value	$ 4,911,312	$ 7,366,968
Accretion of Series C Convertible Preferred Stock to redemption vaule	$ 1,592,341	$ —
Deemed dividend for Series B Convertible Preferred Stock modification	$ —	$ 5,693,000
Accrual of Series B Convertible Preferred Stock and Dividend Redemption	$ —	$ 3,395,945
Warrant liability upon issuance of Series C Convertible Preferred stock	$ 2,797,000	$ —
Derivative liability upon issuance of Series C Convertible Preferred stock	$ 6,096,000	$ —

The accompanying notes are an integral part of these financial statements.

SYNAPTOGENIX, INC.

NOTES TO FINANCIAL STATEMENTS

Note 1 – Organization, Business, Risks and Uncertainties:

Organization and Business

On May 17, 2020, Neurotrope, Inc. ("Neurotrope" or "the Parent") announced plans for the complete legal and structural separation of its wholly owned subsidiary, Neurotrope Bioscience, Inc., from Neurotrope (the "Spin-Off"). Under the Separation and Distribution Agreement, Neurotrope planned to distribute all of its equity interest in this wholly owned subsidiary to Neurotrope's stockholders. Following the Spin-Off, Neurotrope does not own any equity interest in the Company, and the Company operates independently from Neurotrope. On December 7, 2020, the Company became an independent company, Synaptogenix, Inc., a Delaware corporation (formerly known as Neurotrope Bioscience, Inc.) (the "Company" or "Synaptogenix") when the Company filed an amended and restated certificate of incorporation which, among other things, changed its name to Synaptogenix, Inc. The Company's shares of common stock, par value $0.0001 per share (the "Common Stock"), are listed on The Nasdaq Capital Market under the symbol "SNPX."

Neurotrope Bioscience, Inc. was incorporated in Delaware on October 31, 2012 to advance new therapeutic and diagnostic technologies in the field of neurodegenerative disease, primarily Alzheimer's disease ("AD"). The Company is collaborating with Cognitive Research Enterprises, Inc. (formerly known as the Blanchette Rockefeller Neurosciences Institute, or BRNI) ("CRE") in this process. The exclusive rights to certain technology were licensed by CRE to the Company on February 28, 2013 (see Note 3 - Collaborative Agreements and Commitments).

In connection with the separation from Neurotrope, the Company entered into a Separation and Distribution Agreement and several other ancillary agreements. These agreements govern the relationship between the parties after the separation and allocate between the parties' various assets, liabilities, rights and obligations following the separation, including employee benefits, intellectual property, information technology, insurance and tax-related liabilities.

Recent Developments

Exploring Strategic Alternatives

In December 2024, we announced via press release that the board of directors of the Company (the "Board") had formed an independent special committee (the "Special Committee") to explore strategic opportunities to create and enhance value for investors, including promising drug development platforms and/or compelling new technologies and services. Management has reviewed the Company's financial position and has concluded that the Company's continuing financial strength offset by anticipated future burn rate and publicly traded stock as currency allows the Special Committee to have the resources to continue evaluating potential strategic opportunities.

Reverse Stock Split

On April 24, 2023, the Company received a written notice from the Listing Qualifications Department of the Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that for the preceding 30 consecutive business days, the Common Stock did not maintain a minimum closing bid price of $1.00 per share as required by Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company received an initial grace period of 180 calendar days, or until October 23, 2023 (the "Initial Compliance Period"), to regain compliance with the Minimum Bid Price Requirement. On October 24, 2023, the Company received a second written notice from Nasdaq, notifying the Company that it had not regained compliance with the Minimum Bid Price Requirement during the Initial Compliance Period and granting the Company an additional grace period of 180 calendar days, or until April 22, 2024, to regain compliance. On April 4, 2024, the Company effected a one - for - twenty - five reverse stock split of the Common Stock (the "Reverse Stock Split") in order to regain compliance with the Minimum Bid Price Requirement.

On April 22, 2024, Nasdaq informed the Company that it had regained compliance with the Minimum Bid Price Requirement and that the matter was closed.

Liquidity Uncertainties

As of December 31, 2024, the Company had approximately $17.7 million in cash and cash equivalents as compared to $28.7 million at December 31, 2023. The Company expects that its current cash and cash equivalents, approximately $15 million as of the date of this Annual Report, will be sufficient to support its projected operating requirements and financial commitments for at least the next 12 months from this date. The operating requirements include the current development plans for Bryostatin-1, our novel drug candidate targeting the activation of Protein Kinase C Epsilon and other development projects. The financial commitments include the potential redemption of the Series C Convertible Preferred Stock for cash.

The Company expects to need additional capital in order to initiate and pursue potential additional development projects, including the continuing development beyond the ongoing Phase 2 trial of Bryostatin-1. Any additional equity financing, if available, may not be on favorable terms and would likely be significantly dilutive to the Company's current stockholders, and debt financing, if available, may involve restrictive covenants. If the Company is able to access funds through collaborative or licensing arrangements, it may be required to relinquish rights to some of its technologies or product candidates that the Company would otherwise seek to develop or commercialize on its own, on terms that are not favorable to the Company. The Company's ability to access capital when needed is not assured and, if not achieved on a timely basis, will likely have a materially adverse effect on our business, financial condition and results of operations.

Other Risks and Uncertainties

The Company operates in an industry that is subject to rapid technological change, intense competition, and significant government regulation. The Company's operations are subject to significant risk and uncertainties including financial, operational, technological, regulatory, and other risk. Such factors include, but are not necessarily limited to, the results of clinical testing and trial activities, the ability to obtain regulatory approval, the limited supply of raw materials, the ability to obtain favorable licensing, manufacturing, or other agreements, including risk associated with our CRE licensing agreement, and the ability to raise capital to achieve strategic objectives.

CRE has entered into a material transfer agreement with the National Cancer Institute of the National Institutes of Health ("NCI"), pursuant to which the NCI has agreed to supply bryostatin required for the Company's pre-clinical research and clinical trials. This agreement does not provide for a sufficient amount of bryostatin to support the completion of all the clinical trials that the Company is required to conduct in order to seek U.S. Food and Drug Administration ("FDA") approval. Therefore, CRE or the Company would have to enter into one or more subsequent agreements with the NCI for the supply of additional amounts of bryostatin. If CRE or the Company were unable to secure such additional agreements, or if the NCI otherwise discontinues the supply, the Company will have to either secure another source of bryostatin or discontinue its efforts to develop and commercialize Bryostatin-1 for the treatment of AD. In June 2020, the Company entered into a supply agreement (the "Supply Agreement") with BryoLogyx Inc. ("BryoLogyx"), pursuant to which BryoLogyx agreed to be the Company's exclusive supplier of synthetic bryostatin. Pursuant to the terms of the Supply Agreement, the Company received its initial order of one gram of synthetic bryostatin. See Note 3.

Note 2 – Summary of Significant Accounting Policies:

Basis of Presentation:

The accompanying consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP").

The Company is an emerging growth company as the term is used in The Jumpstart Our Business Startups Act, enacted on April 5, 2012 and has elected to comply with certain reduced public company reporting requirements, however, the Company may adopt accounting standards based on the effective dates for public entities.

Use of Estimates:

The preparation of financial statements in conformity with US GAAP requires management to make significant estimates that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Management evaluates its estimates on an ongoing basis using historical

experience and other factors, including the general economic environment and actions it may take in the future. The Company adjusts such estimates when facts and circumstances dictate. However, these estimates may involve significant uncertainties and judgments and cannot be determined with precision. In addition, these estimates are based on management's best judgment at a point in time and as such these estimates may ultimately differ from actual results.

Comprehensive Income (Loss):

The Company follows Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC 220") in reporting comprehensive income (loss). Comprehensive income (loss) is a more inclusive financial reporting methodology that includes disclosure of certain financial information that historically has not been recognized in the calculation of net income (loss). Since the Company has items of other comprehensive income (loss), comprehensive income has been reflected in the Company's financial statements.

Net Earnings or Loss per Share:

Net earnings or loss per share is computed by dividing net income or loss by the weighted-average number of common shares outstanding during the period, excluding shares subject to redemption or forfeiture. The Company presents basic and diluted net earnings or loss per share. Diluted net earnings or loss per share reflect the actual weighted average of common shares issued and outstanding during the period, adjusted for potentially dilutive securities outstanding. Potentially dilutive securities are excluded from the computation of the diluted net earnings or loss per share if their inclusion would be anti-dilutive.

As all potentially dilutive securities are anti-dilutive as of December 31, 2024 and 2023, diluted net loss per share is the same as basic net loss per share for the years ended December 31, 2024 and 2023.

The weighted average dilutive securities that have been excluded from the calculation of diluted net loss per share for the years ended December 31, 2024 and 2023 respectively, because to do so would be anti-dilutive (in common equivalent shares), are as follows:

	December 31, 2024	December 31, 2023
Common stock warrants	694,585	287,197
Common stock options	32,008	28,903
Convertible Preferred Stock	350,264	48,495
Total	1,076,857	364,595

Cash and Cash Equivalents and Concentration of Credit Risk:

The Company considers all highly liquid cash investments with an original maturity of three months or less when purchased to be cash equivalents. At December 31, 2024, the Company's cash balances that exceed the current insured amounts under the Federal Deposit Insurance Corporation ("FDIC") were approximately $0.97 million. In addition, approximately $16.8 million included in cash and cash equivalents were invested in a money market fund, which is not insured under the FDIC.

Investment in Debt Securities

The Company's convertible note receivable was determined to be an available-for-sale debt security under Accounting Standards Codification ("ASC") 320, *Investments,* which was initially recorded at fair value with unrealized holding gains and losses reported in other comprehensive income at each reporting period. The Company estimates the fair value of the convertible note receivable using the income approach, which uses as inputs the fair value of debtor's common stock and estimates for the equity volatility and volume volatility of debtor's common stock, the time to expiration of the convertible note, the discount rate, the stated interest rate compared to the current market rate, the risk-free interest rate for a period that approximates the time to expiration, and probability of default. Therefore, the estimate of expected future volatility is based on the actual volatility of debtor's common stock and historical volatility of debtor's common stock utilizing a lookback period consistent with the time to expiration. The time to expiration is based on the contractual maturity date. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of measurement for time periods approximately equal to the time to expiration. Probability of default is estimated using the S&P Global default rate for companies with a similar credit rating to debtors.

Fair Value of Financial Instruments:

The carrying amounts reflected in the balance sheets for payables approximate fair value due to the short maturities of these instruments. The carrying amounts for warrant liability and derivative liability approximate fair value based on level 3 of the fair value hierarchy.

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy:

Level 1 — Quoted prices in active markets for identical assets or liabilities.

Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable markets.

Level 3 — Unobservable inputs which are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

Assumptions used in the valuation of the Level 3 assets include time to expiration, discount rate, risk-free rate, volatility and probability of default.

Fixed Assets and Leases:

The Company has one lease which has a term of one year during the respective reporting periods. The Company has deemed the lease immaterial and has not recorded it as an obligation on the balance sheet nor a right-of-use asset. The total future expense relating to these leases is approximately $64,000 per year.

Fixed assets are stated at cost less accumulated depreciation. Depreciation is computed on a straight line basis over the estimated useful life of the asset, which is deemed to be between three and ten years.

Research and Development Costs:

All research and development costs, including costs to maintain or expand the Company's patent portfolio licensed from CRE are expensed when incurred. Non-refundable advance payments for research and development are capitalized because the right to receive those services represents an economic benefit. Such capitalized advances will be expensed when the services occur, and the economic benefit is realized. There were no capitalized research and development services, other than non-refundable advance payments as mentioned below, for The Cleveland Clinic Foundation ("Cleveland Clinic"), at December 31, 2024 and December 31, 2023.

Income Taxes:

The Company accounts for income taxes using the asset and liability approach which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and amounts reportable for income tax purposes under the "Separate return method." Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized.

The Company applies the provisions for accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Company has determined that there are no significant uncertain tax positions requiring recognition in the accompanying financial statements. The tax period that is subject to examination by major tax jurisdictions is generally three years from the date of filing.

The Company had federal operating loss carryforwards for income tax purposes of approximately $103.3 million for the period from October 31, 2012 (inception) through December 31, 2024. The net operating loss carryforwards resulted in Federal and state deferred tax assets of approximately $33.0 million at December 31, 2024. Income tax effects of share-based payments are recognized in the financial statements for those awards that will normally result in tax deductions under existing tax law. However, the deferred tax asset is offset by a full valuation allowance.

The Company may be subject to significant U.S. federal income tax-related liabilities with respect to the Spin-Off if there is a determination that the Spin-Off is taxable for U.S. federal income tax purposes. In connection with the Spin-Off, the Company believes that, among other things, the Spin-Off should qualify as a tax-free transaction for U.S. federal income tax purposes under Section 355 and Section 368(a)(1)(D) of the Internal Revenue Code of 1986 (the "Code"). If the conclusions of the tax opinions are not correct, or if the Spin-Off is otherwise ultimately determined to be a taxable transaction, the Company would be liable for U.S. federal income tax related liabilities. Pursuant to the Separation and Distribution Agreement and the Tax Matters Agreement, Neurotrope agreed to indemnify Synaptogenix for certain liabilities, and Synaptogenix agreed to indemnify Neurotrope for certain liabilities, in each case for uncapped amounts. Indemnities that Synaptogenix may be required to provide Neurotrope are not subject to any cap, may be significant and could negatively impact Synaptogenix's business, particularly with respect to indemnities provided in the Tax Matters Agreement. Third parties could also seek to hold Synaptogenix responsible for any of the liabilities that Neurotrope has agreed to retain. Further, the indemnity from Neurotrope may not be sufficient to protect Synaptogenix against the full amount of such liabilities, and Neurotrope may not be able to fully satisfy its indemnification obligations. Moreover, even if Synaptogenix ultimately succeeds in recovering from Neurotrope any amounts for which Synaptogenix is held liable, Synaptogenix may be temporarily required to bear these losses. At December 31, 2023 and as of the date of financial statement issuance date, the Company does not have any indemnification liabilities.

Under Section 382 of the Code, as amended, changes in the Company's ownership may limit the amount of its net operating loss carryforwards that could be utilized annually to offset future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of the Company of more than 50% within a three-year period. In addition, the significant historical operating losses incurred by the Company may limit the amount of its net operating loss carryforwards that could be utilized annually to offset future taxable income, if any. The Company believes that operating loss carryforwards may be limited under Section 382 limitations although Section 382 studies have not been conducted to determine the actual limitations.

The Company has concluded that there are no significant uncertain tax positions requiring recognition in the accompanying financial statements. The tax period that is subject to examination by major tax jurisdictions is generally three years from the date of filing.

A reconciliation of the Company's statutory income tax rate to the Company's effective income tax rate is as follows:

	For the year ended December 31,	
	2024	2023
Loss from continuing operations before taxes on income	$ (12,768,549)	$ (6,038,504)
Tax rate	21 %	21 %
Computed "expected" tax benefit	(2,681,395)	(1,268,086)
State taxes, net of federal income tax benefit	(606,371)	(341,003)
Change in fair value of warrant and derivative liabilities	89,774	(126,475)
Loss on Series C Preferred Stock	800,651	—
Change in valuation allowance	2,779,381	3,892,572
Deferred Rate Change	(272,056)	—
Other adjustments	—	6,115
Return to provision	(109,983)	(2,163,122)
Income tax expense (benefit) attributable to continuing operations	$ —	$ —

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities as of December 31, 2024 and 2023 are as follows:

	For the year ended December 31,	
	2024	2023
Net operating loss carryforward	29,153,925	26,635,550
Stock-based compensation	2,135,087	1,978,436
Depreciation	330	16
Accrued Bonus	73,086	—
Capitalized research costs	1,652,601	1,621,646
Net deferred income tax assets	33,015,029	30,235,648
Less:		
Valuation Allowance	(33,015,029)	(30,235,648)
Net deferred income tax assets	—	—

Recently Adopted Accounting Pronouncements:

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which requires public entities to disclose significant segment expenses and other segment items on an interim and annual basis, and provide in interim periods all disclosures about a reportable segment's profit or loss and assets that are currently required annually. The ASU does not change how a public entity identifies its operating segments, aggregates them, or applies the quantitative threshold to determine its reportable segments. The new disclosure requirements are also applicable to entities that account and report as a single operating segment entity. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024. The Company adopted the guidance for the annual reporting period ended December 31, 2024. There was no impact on the Company's reportable segments identified and additional required disclosures have been included in Note 18, Segment Reporting.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures which requires public entities to disclose specific categories in the effective tax rate reconciliation, as well as expanded disclosures on income taxes paid by jurisdictions. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact related to the adoption of ASU 2023-09 on its financial statement disclosures.

In November 2024, the FASB issued ASU 2024-03, Disaggregation of Income Statement Expenses (Topic 220), which requires disclosure in the notes to financial statements about specific types of expenses included in the expense captions presented on the face of the statement of operations. The requirements of the ASU are effective for annual periods beginning after December 15, 2026, and for interim periods beginning after December 15, 2027, with early adoption permitted. The requirements will be applied prospectively with the option for retrospective application. The Company is currently evaluating the impact related to the adoption of ASU 2024-03 on its financial statement disclosures.

Note 3– Collaborative Agreements and Commitments:

Stanford License Agreements

On May 12, 2014, the Company entered into a license agreement (the "Stanford Agreement") with The Board of Trustees of The Leland Stanford Junior University ("Stanford"), pursuant to which Stanford has granted to the Company a revenue-bearing, world-wide right and exclusive license, with the right to grant sublicenses (on certain conditions), under certain patent rights and related technology for the use of bryostatin structural derivatives, known as "bryologs," for use in the treatment of central nervous system disorders, lysosomal storage diseases, stroke, cardio protection and traumatic brain injury, for the life of the licensed patents. The Company is required to use commercially reasonable efforts to develop, manufacture and sell products ("Licensed Products") in the Licensed Field of Use (as defined in the Stanford Agreement) during the term of the licensing agreement which expires upon the termination of the last valid claim of any licensed patent under this agreement. In addition, the Company must meet specific product development milestones, and upon meeting such milestones, make specific milestone payments to Stanford. The Company must also pay Stanford royalties of 3% of net sales, if any, of Licensed Products (as defined in the Stanford Agreement) and milestone payments

of up to $3.7 million dependent upon stage of product development. As of December 31, 2024, no royalties nor milestone payments have been required.

On January 19, 2017, the Company entered into a second license agreement with Stanford, pursuant to which Stanford has granted to the Company a revenue-bearing, world-wide right and exclusive license, with the right to grant sublicenses (on certain conditions), under certain patent rights and related technology for the use of "Bryostatin Compounds and Methods of Preparing the Same," or synthesized bryostatin, for use in the treatment of neurological diseases, cognitive dysfunction and psychiatric disorders, for the life of the licensed patents. The Company paid Stanford $70,000 upon executing the license and is obligated to pay an additional $10,000 annually as a license maintenance fee. In addition, based upon certain milestones which include product development and commercialization, the Company will be obligated to pay up to an additional $2.1 million and between 1.5% and 4.5% royalty payments on certain revenues generated by the Company relating to the licensed technology. On November 9, 2021, the Company revised the existing licensing agreement with Stanford. The revisions extended all the required future product development and commercialization milestones. The Company is currently in full compliance with the revised agreement and is moving forward on its commitments. The Company has made all required annual maintenance payments. To-date, no royalties nor milestone payments have been earned or made.

The Company has advanced the development of synthetic bryostatin by demonstrating the equivalence of the synthetic to the natural bryostatin product. The estimated cost to initiate and produce sufficient quantities of the synthetic bryostatin drug product is approximately $1.5 million. The Company is evaluating production alternatives at this time.

Mt. Sinai License Agreement

On July 14, 2014, the Company entered into an Exclusive License Agreement (the "Mount Sinai Agreement") with the Icahn School of Medicine at Mount Sinai ("Mount Sinai"). Pursuant to the Mount Sinai Agreement, Mount Sinai granted the Company (a) a revenue-bearing, world-wide right and exclusive license, with the right to grant sublicenses (on certain conditions), under Mount Sinai's interest in certain joint patents held by the Company and Mount Sinai (the "Joint Patents") as well as in certain results and data (the "Data Package") and (b) a non-exclusive license, with the right to grant sublicenses on certain conditions, to certain technical information, both relating to the diagnostic, prophylactic or therapeutic use for treating diseases or disorders in humans relying on activation of Protein Kinase C Epsilon ("PKC ε"), which includes Niemann-Pick Disease (the "Mount Sinai Field of Use"). The Mount Sinai Agreement allows the Company to research, discover, develop, make, have made, use, have used, import, lease, sell, have sold and offer certain products, processes or methods that are covered by valid claims of Mount Sinai's interest in the Joint Patents or an Orphan Drug Designation Application covering the Data Package ("Mount Sinai Licensed Products") in the Mount Sinai Field of Use (as such terms are defined in the Mount Sinai Agreement).

The Company is required to pay Mt. Sinai milestone payments of $2 million upon approval of a new drug approval ("NDA") in the United States and an additional $1.5 million for an NDA approval in the European Union or Japan. In addition, the Company is required to pay Mt. Sinai royalties on net sales of licensed product of 2.0% for up to $250 million of net sales and 3.0% of net sales over $250 million. Since inception, the Company has paid Mt. Sinai approximately $210,000 consisting of licensing fees of $135,000 plus development costs and patent fees of approximately $75,000. As of December 31, 2023, no royalties nor milestone payments have been required.

Agreements with BryoLogyx

On June 9, 2020, the Company entered into a supply agreement (the "Supply Agreement") with BryoLogyx Inc. ("BryoLogyx"), pursuant to which BryoLogyx agreed to serve as the Company's exclusive supplier of synthetic bryostatin. Pursuant to the terms of the Supply Agreement, the Company placed an initial order and subsequently received one gram of current good manufacturing practice ("cGMP") synthetic bryostatin as an active pharmaceutical ingredient to be used in a drug product ("API"). The Company may place additional orders for API beyond the initial order by making a written request to BryoLogyx no later than six months prior to the requested delivery date. The Company is not currently using synthetic bryostatin for its ongoing Phase 2 clinical trial and will determine when to incorporate the synthetic into the clinical trial process.

In connection with the Supply Agreement, on June 9, 2020, the Company entered into a transfer agreement (the "Transfer Agreement") with BryoLogyx. Pursuant to the terms of the Transfer Agreement, the Company agreed to assign and transfer to BryoLogyx all of the Company's right, title and interest in and to that certain Cooperative Research and Development Agreement, dated as of January 29, 2019 (the "CRADA"), by and between the Company and the U.S. Department of Health and Human Services, as

represented by the NCI, under which Bryostatin-1's ability to modulate CD22 in patients with relapsed/refractory CD22+ disease has been evaluated to date. Pursuant to guidance provided by NCI, the Company CRADA has been cancelled and BryoLogyx has initiated a request for a new CRADA in its name. BryoLogyx will be filing its own investigational new drug application ("IND") for CD22 with the FDA. As consideration for the transfer of rights to the CRADA, BryoLogyx has agreed to pay to the Company 2% of the gross revenue received in connection with the sale of bryostatin products, up to an aggregate payment amount of $1 million. No such revenues have been earned as of December 31, 2023.

Nemours Agreement

On September 5, 2018, we announced a collaboration with Nemours A.I. DuPont Hospital ("Nemours"), a premier U.S. children's hospital, to initiate a clinical trial in children with Fragile X, a genetic disorder. In addition to the primary objective of safety and tolerability, measurements will be made of working memory, language, and other functional aspects such as anxiety, repetitive behavior, executive functioning, and social behavior. On August 5, 2021, the Company announced its memorandum of understanding with Nemours to initiate a clinical trial using Bryostatin-1, under Orphan Drug Status, to treat Fragile X. The Company intends to provide the Bryostatin-1 and obtain the IND and Nemours intends to provide the clinical site and attendant support for the trial. The Company and Nemours, jointly, will develop the trial protocol. The Company estimates its total trial and IND cost to be approximately $2 million. As of the end of the period covered by this Annual Report on Form 10-K, the Company has incurred cumulative expenses associated with this agreement of approximately $100,000.

The Company has filed for an IND with the FDA. The FDA has placed the development of the IND on clinical hold pending completion of further analytics relating to drug pharmacokinetics and pharmacodynamics. The Company is currently evaluating its plans to advance Fragile X development.

Cleveland Clinic

On February 23, 2022, the Company announced its collaboration with the Cleveland Clinic to pursue possible treatments for Multiple Sclerosis ("MS"), and on July 19, 2023, the Company announced that it had entered into an agreement with the Cleveland Clinic to conduct a Phase 1 trial of Bryostatin-1 in MS. Pursuant to the agreement, the Cleveland Clinic was obligated to manage the clinical trial's implementation, including the IND submission to the FDA which was filed during the fourth quarter of 2023 and future patient enrollment upon approval of the IND submission. The total estimated costs associated with this collaboration are approximately $2.0 million. As of December 31, 2024, the Company has paid or incurred costs with the Cleveland Clinic of approximately $528,000.

In December 2024, the Company announced via press release the termination of its agreement with the Cleveland Clinic due to the slow pace of enrollment in the Phase 1 clinical trial. The termination of the agreement was one of various actions authorized by the Board, designed to reduce cash burn rate.

Strategic Investment in Debt and Equity Securities of Cannasoul

On October 31, 2023, the Company entered into a share purchase agreement (the "Purchase Agreement") with Cannasoul Analytics Ltd. ("Cannasoul"), pursuant to which the Company agreed to purchase from Cannasoul (i) 12,737 shares of Cannasoul's Series A preferred shares (the "Preferred Shares"), representing 5% of Cannasoul's issued and outstanding share capital, at a price of $44.1550 per Preferred Share for $562,402 and (ii) a convertible preferred note in an aggregate amount of up to $1,437,598 (the "Initial Convertible Note") convertible into 32,648 Preferred Shares. The Preferred Shares are convertible (i) any time after the date of issuance at the Company's option and (ii) automatically upon the earlier of a payment default, the consummation of Cannasoul's IPO, or the majority consent of the majority holders of the Preferred Shares.

Additionally, the Company agreed to purchase up to four additional convertible preferred notes in a total amount of up to approximately $2,000,000 (or approximately $500,000 per convertible preferred note), subject to Cannasoul achieving certain revenue and expense goals (the "Milestones") over the next four quarters (the "Milestone Convertible Notes") as set forth in the Purchase Agreement. The Company's purchase of the Preferred Shares, the Initial Convertible Notes and the Milestone Convertible Notes is herein referred to as the "Investment." If Cannasoul fails to achieve a Milestone, the Company will not be obligated to purchase the applicable Milestone Convertible Note. If Cannasoul achieves a Milestone and the Company fails to purchase the applicable Milestone Convertible Note, Cannasoul will have the right to convert all the Company's Preferred Shares into Cannasoul's ordinary shares and the Company will lose certain board appointment rights and certain rights in Cannasoul's subsidiaries.

In connection with the Purchase Agreement, Cannasoul adopted amended and restated articles of incorporation (the "Cannasoul Charter"). Pursuant to the Cannasoul Charter, the Company has a number of rights as investor, including (i) the right to appoint and dismiss three of the seven members of Cannasoul's board of directors and veto power with respect to a fourth member, (ii) preemptive rights to participate pro rata in any pre-initial public offering financings by Cannasoul, (iii) rights of first refusal with respect to transfers of Cannasoul ordinary shares by other investors, (iv) rights of co-sale with respect to proposed sales or transfers of Cannasoul ordinary shares by certain key investors, (v) veto rights with respect to certain major transactions, any amendment to the Cannasoul Charter, approval of Cannasoul's budget and other items.

It was determined that Cannasoul is considered a variable interest entity ("VIE"), but the Company lacks the power to direct the activities that most significantly influence the VIE's economic performance. As such, the Company is not the primary beneficiary of the VIE and is not required to consolidate Cannasoul in accordance with ASC 810-10-25-38A.

The Company's investment in the Preferred Shares represents an investment in an equity security in accordance with ASC 320. The Preferred Shares are convertible at any time after the date of issuance, automatically upon a payment default, an IPO, or the written consent of the holders of a majority of the Preferred Shares. The conversion price is subject to traditional anti-dilution adjustments. The Company will account for its investment in Cannasoul's Preferred Shares under the equity method of accounting as it was determined the Company has significant influence over Cannasoul based on its board representation and other veto rights per ASC 323-10-15-6 to 8. The Company has elected to record the equity in earnings of the equity method investment on a three-month lag which is recognized in other comprehensive income. As a result, the Company recorded a loss on its equity method investment of $44,525 and $0 during the years ended December 31, 2024 and 2023, respectively.

The Initial Convertible Note receivable is not traded in active markets and the fair value was determined using a probability weighted scenario-based model. The Initial Convertible Note receivable is accounted for as an available-for-sale debt security based on "Level 3" inputs, which consist of unobservable inputs and reflect management's estimates of assumptions that market participants would use in pricing the asset (i.e., implied market rate, risk free rate, share price, and probability of scenarios). Holding gains and losses are recorded in other comprehensive income.

As of December 31, 2024, Cannasoul had achieved two Milestones and accordingly the Company purchased two Milestone Convertible Notes for an aggregate of $500,000 and $500,000, respectively, in January and June 2024.

Below is a summary of activity for the Milestone Convertible Notes as of December 31, 2024:

Balance of Initial Convertible Note as of January 1, 2023	$ —
Issued	1,438,500
Balance of Initial Convertible Note as of December 31, 2023	1,438,500
Issued	1,000,000
Write-off of investment	(2,438,500)
Balance of Initial Convertible Note as of December 31, 2024	$ —

As of the filing of this 10-K report, Cannasoul has shut down operations and retains investments in several early, development-stage companies that are deemed to also have no value. As a result, the Company was written off its debt and equity investments in Cannasoul.

Cognitive Research Enterprises, Inc. ("CRE")

Effective October 31, 2012, the Company executed a Technology License and Services Agreement (the "TLSA") with CRE, a related party, and NRV II, LLC ("NRV II"), another affiliate of CRE, which was amended by Amendment No. 1 to the TLSA as of August 21, 2013, as amended and restated on February 4, 2015 (the "CRE License Agreement"). Pursuant to the CRE License Agreement, CRE and NRV II provide research services and have granted the Company the exclusive and nontransferable world-wide, royalty-bearing right, with a right to sublicense (in accordance with the terms and conditions described below), under CRE's and NRV II's respective right, title and interest in and to certain patents and technology owned by CRE or licensed to NRV II by CRE as of or subsequent to October 31, 2012, to develop, use, manufacture, market, offer for sale, sell, distribute, import and export certain products or services for therapeutic applications for AD and other cognitive dysfunctions in humans or animals (the "Field of Use"). Additionally, the CRE License Agreement specifies that all patents that issue from a certain patent application shall constitute licensed patents and all

trade secrets, know-how and other confidential information claimed by such patents constitute licensed technology under the CRE License. The CRE License Agreement terminates on the later of the date (a) the last of the licensed patent expires, is abandoned, or is declared unenforceable or invalid or (b) the last of the intellectual property enters the public domain.

After Neurotrope's initial Series A Stock financing, the CRE License Agreement required the Company to enter into scope of work agreements with CRE as the preferred service provider for any research and development services or other related scientific assistance and support services. There were no such statements of work agreements entered into during the years ended December 31, 2024 and 2023, respectively.

In addition, on November 10, 2018, the Company and CRE entered into a second amendment (the "Second Amendment") to the TLSA pursuant to which CRE granted certain patent prosecution and maintenance rights to the Company. Under the Second Amendment, the Company will have the sole and exclusive right and the obligation, to apply for, file, prosecute and maintain patents and applications for the intellectual property licensed to the Company, and pay all fees, costs and expenses related to the licensed intellectual property.

Note 4 – Related Party Transactions:

Related Party Agreements

On August 4, 2016, Neurotrope, Inc. entered into a consulting agreement with SM Capital Management, LLC ("SMCM"), a limited liability company owned and controlled by the Company's Chairman of the Board, Mr. Joshua N. Silverman (the "Consulting Agreement"). Pursuant to the Consulting Agreement, SMCM shall provide consulting services which shall include, but not be limited to, providing business development, financial communications, and management transition services, for a one-year period, subject to annual review thereafter. SMCM's annual consulting fee is $120,000, payable by the Company in monthly installments of $10,000. This contract was assigned to Synaptogenix, Inc. as of December 1, 2020. For the years ended December 31, 2024 and 2023, $120,000 is reflected in the Company's statements of comprehensive loss, respectively, pursuant to the Consulting Agreement.

Note 5 – Other Commitments:

Clinical Trial Services Agreements

On July 23, 2020, the Company entered into the 2020 Services Agreement with WCT. The 2020 Services Agreement relates to services for the ongoing Phase 2 clinical trial assessing the safety, tolerability, and long-term efficacy of Bryostatin-1 in the treatment of moderately severe AD subjects not receiving memantine treatment (the "2020 Study"). On January 22, 2022, the Company executed a change order with WCT to accelerate trial subject recruitment for which costs totaled approximately $1.4 million. In addition, on February 10, 2022, the Company signed an additional agreement with a third-party vendor to assist with the increased trial recruitment retention with costs totaling approximately $1.0 million which was subsequently canceled with no charges incurred by the Company. In addition, on September 11, 2023, the Company signed an agreement with WCT to assist with documenting the trial results which costs totaled approximately $300,000. The updated total estimated budget for the current trial services, including pass-through costs, was approximately $11.3 million. As noted below, the Company was granted a $2.7 million award from the National Institutes of Health, which award was used to support the Phase 2 Study, resulting in an estimated net budgeted cost of the Phase 2 Study to Neurotrope of $9.3 million. The Company may terminate the 2020 Services Agreement without cause upon 60 days' prior written notice.

The Company was awarded a $2.7 million grant from the NIH, which will be used to support the 2020 Study, resulting in an estimated net budgeted cost of the 2020 Study to the Company of $8.3 million. The NIH grant provided for funds in the first year, which began in April 2020, of approximately $1.0 million and funding in year two, which began April 2021, of approximately $1.7 million. As of February 22, 2022, virtually all the NIH grant had been received and offset against the clinical trial costs. The Company incurred approximately $11.2 million of cumulative expenses associated with the current Phase 2 clinical trial as of December 31, 2023. Of the total $11.2 million incurred for the trial as of December 31, 2024, approximately $0 and $560,000 is reflected in the statement of comprehensive loss for the years ended December 31, 2024 and 2023, respectively.

Employment Agreements

On December 7, 2020, the Company entered into an offer letter (the "Offer Letter") with Alan J. Tuchman, M.D., pursuant to which Dr. Tuchman agreed to serve as the Company's Chief Executive Officer, commencing on December 7, 2020. In addition, in connection with his appointment as the Company's Chief Executive Officer, Dr. Tuchman was appointed to the board of directors of the Company. Dr. Tuchman receives an annual base salary of $222,000, with an annual discretionary bonus of up to 50% of his base salary then in effect. The term of Dr. Tuchman's employment pursuant to the Offer Letter is one year, which shall be extended automatically for six - month periods unless either party gives timely written notice. On June 20, 2024, the Company entered into a third amendment to the Offer Letter to extend the term of Dr. Tuchman's employment through December 7, 2024. with automatic monthly renewals thereafter unless earlier terminated by either party. In November 2024, the Company's Board of Directors amended Dr. Tuchman's base salary to $12,500 per month, effective January 1, 2025. Pursuant to the Offer Letter, if Dr. Tuchman is terminated without cause, Dr. Tuchman shall be entitled to severance equal to six months of Dr. Tuchman's annual base salary, payable in the form of a salary continuation over the six-month period following his termination.

See Notes 3 and 4 for Collaboration and License Agreement related commitments.

Contingencies

Pursuant to the Separation Agreement and Tax Matters Agreement between the Company and its predecessor Neurotrope, Neurotrope agreed to indemnify Synaptogenix for certain liabilities. The Company agreed to indemnify Neurotrope for certain liabilities, in each case for uncapped amounts. Indemnities that the Company may be required to provide Neurotrope are not subject to any cap, may be significant and could negatively impact the Company's business, particularly with respect to indemnities provided in the Tax Matters Agreement. Third parties could also seek to hold the Company responsible for any of the liabilities that Neurotrope has agreed to retain. Further, the indemnity from Neurotrope may not be sufficient to protect the Company against the full amount of such liabilities, and Neurotrope may not be able to fully satisfy its indemnification obligations. Moreover, even if the Company ultimately succeeds in recovering from Neurotrope any amounts for which the Company is held liable, the Company may be temporarily required to bear these losses ourselves. As of the reporting date, there are no claims relating to the indemnification agreement.

Note 6 – Stockholders' Equity:

The Company's certificate of incorporation authorizes it to issue 150,000,000 shares of Common Stock and 1,000,000 shares of preferred stock, par value $0.0001 per share.

The holders of Common Stock are entitled to receive dividends out of assets or funds legally available for the payment of dividends at such times and in such amounts as the Board from time to time may determine. To date, the Company has not paid dividends on its Common Stock. Holders of Common Stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders. There is no cumulative voting of the election of directors then standing for election. The Common Stock is not entitled to pre-emptive rights and is not subject to conversion or redemption. Upon liquidation, dissolution or winding up of the Company, the assets legally available for distribution to stockholders are distributable ratably among the holders of Common Stock after payment of liabilities, accrued dividends and liquidation preferences, if any. Each outstanding share of Common Stock is duly and validly issued, fully paid and non-assessable.

November 2022 Private Placement

On November 17, 2022, the Company entered into the November Purchase Agreement with the November Investors, pursuant to which we agreed to sell to the November Investors (i) an aggregate of 15,000 shares of Series B Preferred Stock and (ii) warrants to acquire up to an aggregate of 77,420 shares of Common Stock. The Company received total gross proceeds of approximately $15 million from the Series B Offering.

The Series B Preferred Stock matured on September 9, 2024, and no shares of Series B Preferred Stock remain outstanding. The terms of the Series B Preferred Stock were as set forth in the Certificate of Designations of Series B Convertible Preferred Stock (the "Series B Certificate of Designations"). The Company was required to redeem the Series B Preferred Stock in 15 equal monthly installments, commencing on June 1, 2023 and issued an aggregate of 1,042,027 shares of Common Stock to redeem the Series B Preferred Stock.

The holders of the Series B Preferred Stock were entitled to dividends of 7% per annum, compounded monthly, which were payable in cash or shares of Common Stock at our option, in accordance with the terms of the Series B Certificate of Designations.

Notwithstanding the foregoing, the Company's ability to settle conversions and make amortization payments using shares of Common Stock was subject to certain limitations set forth in the Series B Certificate of Designations, including a limit on the number of shares that may be issued until the Nasdaq Stockholder Approval. The Company received Nasdaq Stockholder Approval at the Company's special meeting of stockholders held on April 14, 2023.

The Series B Warrants are exercisable for Series B Warrant Shares at an initial exercise price of $2.8586 per share (as adjusted from time to time pursuant to the terms of the Series B Warrants, the "Series B Exercise Price") and expire five years from the date of issuance. The Series B Exercise Price was reduced based upon the Reverse Stock Split and the Series C Private Placement (see below). The Series B Exercise Price is subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment, on a "full ratchet" basis, in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable Series B Exercise Price (subject to certain exceptions).

During the year ended December 31, 2024, the Company redeemed $6,000,000 of the Series B Preferred Stock and $396,640 of accrued dividends through a combination of cash through installment redemption and by issuing 374,219 shares of our Common Stock through installment conversions and proportionately relieved $4,911,312 of discount related to the redeemed Series B Preferred Stock. During the year ended December 31, 2024, the Company recognized a deemed dividend of $271,086 related to cash premiums.

During the year ended December 31, 2023, we redeemed $9,000,000 of the Series B Preferred Stock and $1,022,149 of accrued dividends through a combination of cash through installment redemption and by issuing 585,908 shares of our Common Stock through installment conversions and proportionately relieved $7,366,968 of discount related to the redeemed Series B Preferred Stock. During the year ended December 31, 2023, we recognized a deemed dividend of $140,374 related to cash premiums and true-up conversion shares in excess of the pre-amortization installment amounts and issued 81,901 shares of our Common Stock in satisfaction of the deemed dividend.

In connection with the November Private Placement, pursuant to an Engagement Letter, between the Company and Katalyst Securities LLC (the "November Placement Agent"), the Company paid the November Placement Agent (i) a cash fee equal to 7% of the gross proceeds from any sale of securities in the November Private Placement and (ii) warrants to purchase shares of Common Stock equal to 3% of the number of shares of Common stock that the Series B Preferred Shares are initially convertible into, with an exercise price of $193.75 per share and a five-year term.

September 2024 Private Placement

On September 10, 2024, we entered into the Series C Purchase Agreement with the Series C Investors, pursuant to which we agreed to sell to the Series C Investors (i) in a registered direct offering, an aggregate of 1,793 shares of Series C Preferred Stock, initially convertible into up to 448,250 Registered Conversion Shares and (ii) in a concurrent private placement, an aggregate of 3,207 shares of Series C Preferred Stock, initially convertible into up to 801,750 Unregistered Conversion Shares as well as Series C Warrants to acquire up to an aggregate of 1,250,000 Series B Warrant Shares.

GP Nurmenkari Inc. acted as the Series C Placement Agent. In connection with the Series C Offering, pursuant to an Engagement Letter between the Company and the Series C Placement Agent, we agreed to pay the Series C Placement Agent (i) a cash fee equal to 7.0% of the gross proceeds from any sale of securities in the Series C Offering and (ii) warrants to purchase shares of Common Stock equal to 3.0% of the number of shares of Common Stock that the Series C Preferred Stock are initially convertible into, with an exercise price of $4.00 per share and a five-year term.

The terms of the Series C Preferred Stock are as set forth in the Series C Certificate of Designations, which was filed with the Secretary of State for the State of Delaware on September 12, 2024. The Series C Preferred Stock is convertible into Series C Conversion Shares at the election of the holder at any time at the Series C Conversion Price. The Series C Conversion Price is subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable Series C Conversion Price (subject to certain exceptions). We are required to redeem the Series C Preferred Shares in equal

quarterly installments, commencing on October 31, 2024. The amortization payments due upon such redemption are payable in cash at 107% of the applicable Installment Amount (as defined in the Series C Certificate of Designations).

The holders of the Series C Preferred Shares are entitled to dividends of 5% per annum, compounded quarterly, which will be payable in cash. Upon the occurrence and during the continuance of a Triggering Event (as defined in the Series C Certificate of Designations), the Series C Preferred Shares will accrue dividends at the rate of 15% per annum. The holders of Series C Preferred Shares are entitled to vote with holders of the Common Stock as a single class on all matters that holders of Common Stock are entitled to vote upon, with the number of votes per Series C Preferred Share equal to the stated value of such Series C Preferred Share divided by the "Minimum Price" (as defined in Rule 5635 of the Listing Rules of the Nasdaq Stock Market) immediately prior to the date of the Series C Purchase Agreement.

Following the first anniversary of the initial issuance of the Series C Preferred Shares through the date that is ten calendar days thereafter, holders of Series C Preferred Shares may require the Company to redeem all or any portion of their Series C Preferred Shares in cash, pursuant to the terms set forth in the Series C Certificate of Designation.

Notwithstanding the foregoing, the Company's ability to settle conversions is subject to certain limitations set forth in the Certificate of Designations, including a limit on the number of shares that may be issued until the time, if any, that the Company receives Nasdaq Stockholder Approval. The Company received Nasdaq Stockholder Approval of these matters at a meeting held on December 6, 2024. Further, the Series C Certificate of Designations contains a certain beneficial ownership limitation after giving effect to the issuance of shares of Common Stock issuable upon conversion of the Series C Certificate of Designations or Series C Warrants.

The Series C Certificate of Designations includes certain Triggering Events (as defined in the Series C Certificate of Designations), including, among other things, the failure to file and maintain an effective registration statement covering the sale of the holder's securities registrable pursuant to the Series C Registration Rights Agreement (defined below) and the Company's failure to pay any amounts due to the holders of the Series C Preferred Shares when due. In connection with a Triggering Event, each holder of Series C Preferred Shares will be able to require the Company to redeem in cash any or all of the holder's Series C Preferred Shares at a premium set forth in the Series C Certificate of Designations.

The Company is subject to certain affirmative and negative covenants regarding the incurrence of indebtedness, acquisition and investment transactions, the existence of liens, the repayment of indebtedness, the payment of cash in respect of dividends (other than dividends pursuant to the Series C Certificate of Designations), distributions or redemptions, and the transfer of assets, among other matters.

The Series C Warrants are exercisable immediately at the Series C Exercise Price and expire five years from the date of issuance. The Series C Exercise Price is subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment, on a "full ratchet" basis, in the event of any issuances of Common Stock, or securities convertible, exercisable or exchangeable for Common Stock, at a price below the then-applicable Series C Exercise Price (subject to certain exceptions). There is no established public trading market for the Series C Warrants and the Company does not intend to list the Series C Warrants on any national securities exchange or nationally recognized trading system.

In connection with the Series C Purchase Agreement, on September 10, 2024, the Company and the Series C Investors entered into a Registration Rights Agreement, pursuant to which the Company was required to file a resale registration statement with the SEC to register for resale 200% of the Unregistered Conversion Shares and 200% of the Series C Warrant Shares. The Company filed a registration statement for the resale of such securities on October 10, 2024, which was declared effective by the SEC on October 21, 2024. The Company also agreed to other customary obligations regarding registration, including indemnification and maintenance of the effectiveness of the registration statement.

During the year ended December 31, 2024, the Company redeemed $715,000 of the Series C Preferred Stock and $34,247 of accrued dividends in cash through installment redemption and proportionately relieved $1,592,341 of discount related to the redeemed Series C Preferred Stock. During the year ended December 31, 2024, the Company recognized a deemed dividend of $52,447 related to cash premiums.

During January 2025, the Company redeemed $715,000 of the Series C Preferred Stock and $53,563 of accrued dividends in cash through installment redemption.

Accounting Treatment of November 2022 Private Placement

Series B Preferred Shares

Effective March 17, 2023, the Company filed the First CoD Amendment. The First CoD Amendment modified (i) the definition of Floor Price to mean the lower of (i) $1.25 and (ii) 20% of the "Minimum Price" (as defined in Rule 5635 of the Listing Rules of the Nasdaq Stock Market) on the date of receipt of Stockholder Approval (as defined in the Agreement), (ii) the definition of Installment Date to mean June 1, 2023, and thereafter, the first Trading Day of each calendar month immediately following the previous Installment Date until the Maturity Date, and the Maturity Date, and (iii) the definition of Maturity Date to mean August 31, 2023. In accordance with ASC 470-50 and 470-60, the Company has made an accounting policy election to account for amendments of the Series B Preferred Stock as modifications or extinguishments based on the change in fair value of the instrument immediately before and immediately after the amendment. The Company accounted for the First CoD Amendment as an extinguishment as the change in fair value of the Series B Preferred Stock was 34% (greater than ten percent (10%)) immediately before and immediately after. In accordance with ASC 260-10-S99-2, the Company recognized the $5.7 million increase in fair value as a deemed dividend on the statement of comprehensive loss.

On May 11, 2023, the Company filed the Second CoD Amendment. The Second CoD Amendment removed the definition of Make-Whole Amount (as was previously defined in the Agreement) and modified the definition of the Conversion Amount so as to remove the Make-Whole Amount from said definition. In accordance with ASC 470-50 and 470-60, the Company accounted for the amendment as a modification as the change in fair value of the Series B Preferred Stock was 0.05% (less than ten percent (10%)) immediately before and immediately after. The Company analogized to the share-based payments model for the appropriate modification accounting and did not recognize a deemed dividend as the fair value decreased upon modification.

The Preferred Shares were determined to be more akin to a debt-like host than an equity-like host. The Company identified the following embedded features that are not clearly and closely related to the debt host instrument: 1) make-whole interest upon a contingent redemption event, 2) make-whole interest upon a conversion event, 3) an installment redemption upon an Equity Conditions Failure (as defined in the Certificate of Designation), and 4) variable share-settled installment conversion. These features were bundled together, assigned probabilities of being affected and measured at fair value. Subsequent changes in fair value of these features are recognized in the statement of comprehensive loss. The Company estimated the $2.2 million fair value of the bifurcated embedded derivative at issuance using a Monte Carlo simulation model, with the following inputs: the fair value of our common stock of $6.52 on the issuance date, estimated equity volatility of 85.0%, estimated traded volume volatility of 255.0%, the time to maturity of 1.61 years, a discounted market interest rate of 7.3%, dividend rate of 7%, a penalty dividend rate of 15.0%, and probability of default of 8.2%. The fair value of the bifurcated derivative liability was estimated utilizing the with and without method which uses the probability weighted difference between the scenarios with the derivative and the plain vanilla maturity scenario without a derivative.

The discount to the fair value is included as a reduction to the carrying value of the Series B Preferred Shares. During 2022, the Company recorded a total discount of approximately $12.3 million upon issuance of the Series B Preferred Shares, which was comprised of the issuance date fair value of the associated embedded derivative of approximately $2.2 million, stock issuance costs of approximately $0.5 million and the fair value of the Warrants of approximately $9.6 million . It was deemed probable that the Series B Preferred Shares will be redeemed for Common Stock upon Installment Redemptions (as defined the Certificate of Designations). As such, the Company recognized approximately $7.4 million to additional paid-in capital to accrete the Series B Preferred Shares to redemption amount pursuant to ASC 480-10-S99-3A with a corresponding increase in the carrying value of the Series B Preferred Shares.

During the year ended December 31, 2024 and 2023, the Company recorded a gain of approximately $1.1 million and a loss of approximately $(0.7) million, respectively, related to the change in fair value of the derivative liability which is recorded in other income (expense) on the statements of comprehensive loss.

Series B Common Stock Warrants

Pursuant to the Private Placement, the Company issued to investors Warrants and, pursuant to its advisory agreements, the Company issued to its advisor additional Warrants with the same terms. The Broker Warrants are within the scope of ASC 718 pursuant to ASC 718-10-20 but are subject to liability classification as they would be required to be classified as liabilities in accordance with ASC 480.

The Warrants were determined to be within the scope of ASC 480-10 as they are puttable to the Company at Holders' election upon the occurrence of a Fundamental Transaction (as defined in the agreements). As such, the Company recorded the Warrants as a liability at fair value with subsequent changes in fair value recognized in earnings. The fair value of the Warrants of approximately $9.9 million was estimated at the date of issuance using the Black-Scholes Model with the following weighted average assumptions: dividend yield 0%; expected term of five years; equity volatility of 105%; and a risk-free interest rate of 3.97%.

Transaction costs incurred attributable to the issuance of the Warrants of $0.9 million were immediately expensed in accordance with ASC 480.

During the years ended December 31, 2024 and 2023, the Company recorded a loss of approximately $170,000 and $1.4 million, respectively, related to the change in fair value of the warrant liability which is recorded in other income (expense) on the statements of comprehensive loss. The fair value of the Warrants of approximately $0.3 million was estimated at December 31, 2024 utilizing the Black Scholes Model using the following weighted average assumptions: dividend yield 0%; remaining term of 2.89 years; equity volatility of 115%; and a risk-free interest rate of 4.18%.

Accounting Treatment of September 2024 Private Placement

Series C Preferred Shares

The Series C Preferred Shares were determined to be more akin to a debt-like host than an equity-like host. The Company identified the following embedded features that are not clearly and closely related to the debt host instrument: 1) certain contingent redemption options and 2) variable share-settled installment conversions. These features were bundled together, assigned probabilities of being affected and measured at fair value. Subsequent changes in fair value of these features are recognized in the statements of comprehensive loss. The Company estimated the approximately $6.1 million fair value of the bifurcated embedded derivative at issuance using a discounted cash flow scenario model, with the following inputs: the fair value of our common stock of $2.85 on the issuance date, estimated equity volatility of 90.0%, the time to maturity of 1.57 years, the installment redemption premium of 107%, a market interest rate of 5.53%, a risk-free rate of 3.76%, and dividend rate of 5%. The fair value of the bifurcated derivative liability was estimated utilizing the with and without method which uses the probability weighted difference between the scenarios with the derivative and the plain vanilla maturity scenario without a derivative.

The discount to the fair value is included as a reduction to the carrying value of the Series C Preferred Shares. During 2024, the Company recorded a total discount of approximately $5 million upon issuance of the Series C Preferred Shares as the fair value of the liabilities required to be remeasured at fair value exceeded the gross proceeds. The Company recognized the excess of the fair value of the total of these liabilities over the proceeds received as a loss upon issuance of preferred stock of $3.8 million which is included in other income (expense) in the statements of comprehensive loss. Upon issuance it was deemed probable that the Series C Preferred Shares will be redeemed; the Company therefore recorded accretion expense of approximately $1.6 million during the year ended December 31, 2024 to adjust the Series C Preferred Shares to their redemption amount pursuant to ASC 480-10-S99-3A.

During the year ended December 31, 2024, the Company recorded a loss of $81,000 related to the change in fair value of the derivative liability corresponding to the Series C Preferred Shares which is recorded in other income (expense) on the statements of comprehensive loss. The Company estimated the approximately $6.2 million fair value of the bifurcated embedded derivative as of December 31, 2024 using a discounted cash flow scenario model, with the following inputs: the fair value of our common stock of $3.47 on the valuation date, estimated equity volatility of 90.0%, the time to maturity of 1.19 years, the installment redemption premium of 107%, a market interest rate of 6.13%, a risk-free rate of 4.1%, and dividend rate of 5%. The fair value of the bifurcated derivative liability was estimated utilizing the with and without method which uses the probability weighted difference between the scenarios with the derivative and the plain vanilla maturity scenario without a derivative.

Series C Common Stock Warrants

Pursuant to the Private Placement, the Company issued to investors Series C Warrants to purchase 1,250,000 shares of Common Stock, with an exercise price of $4.00 per share (subject to adjustment), for a period of five years from the date of issuance. Pursuant to its advisory agreements, the Company issued to its advisor additional Series C Warrants to purchase 37,500 shares of Common Stock with the same terms (the "Series C Broker Warrants"). The Series C Broker Warrants are within the scope of ASC 718 pursuant to ASC 718-10-20 but are subject to liability classification as they would be required to be classified as liabilities in accordance with ASC 480.

The Series C Warrants were determined to be within the scope of ASC 480-10 as they are puttable to the Company at Holders' election upon the occurrence of a Fundamental Transaction (as defined in the agreements). As such, the Company recorded the Series C Warrants as a liability at fair value with subsequent changes in fair value recognized in earnings. The Company utilized the Black Scholes Model to calculate the value of these warrants issued during the year ended December 31, 2024. The fair value of the Series C Warrants of approximately $2.8 million was estimated at the date of issuance using the following weighted average assumptions: dividend yield 0%; expected term of five years; equity volatility of 110%; and a risk-free interest rate of 3.41%.

Transaction costs incurred attributable to the issuance of the Warrants of $0.6 million, which includes the issuance date fair value of the Series C Broker Warrants of approximately $0.1 million, were immediately expensed in accordance with ASC 480.

During the year ended December 31, 2024, the Company recorded a loss of approximately $0.7 million related to the change in fair value of the warrant liability which is recorded in other income (expense) on the statements of comprehensive loss. The fair value of the Series C Warrants of approximately $3.5 million was estimated at December 31, 2024 utilizing the Black Scholes Model using the following weighted average assumptions: dividend yield 0%; remaining term of 4.7 years; equity volatility of 110%; and a risk-free interest rate of 4.27%.

Note 7 – Stock Based Compensation:

2020 Equity Incentive Plan

Upon completion of the Spin-Off, the Company's 2020 Equity Incentive Plan (the "2020 Plan") became effective on December 7, 2020. The total number of securities available for grant under the 2020 Plan was 10,000 shares of Common Stock, subject to adjustment. On April 7, 2021, the Company held a special meeting of stockholders ("Special Meeting"). At the Special Meeting, the Company's stockholders approved an amendment to the Company's 2020 Plan to increase the total number of shares of Common Stock from 10,000 to an aggregate of 25,000 shares of Common Stock. On October 11, 2022, the Company held its annual meeting of stockholders at which the Company's stockholders approved an amendment to the Company's 2020 Plan to increase the total number of shares of Common Stock authorized for issuance from 25,000 to an aggregate of 55,000 shares. On December 20, 2023, the Company held its annual meeting of stockholders at which time the Company's stockholders approved an amendment to the Company's 2020 Plan was amended to increase the total number of shares of Common Stock authorized for issuance from 55,000 to an aggregate of 4,175,000 shares.

The Compensation Committee of the Company's board of directors (the "Committee") will administer the 2020 Plan and have full power to grant stock options and Common Stock, construe and interpret the 2020 Plan, establish rules and regulations, and perform all other acts, including the delegation of administrative responsibilities, as it believes reasonable and proper. The Committee, in its absolute discretion, may award Common Stock to employees, consultants, and directors of the Company, and such other persons as the Committee may select, and permit holders of options to exercise such options prior to full vesting.

Stock and Option Grants

The following is a summary of stock option activity under the stock option plans for the year ended December 31, 2024:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in millions)
Options outstanding at January 1, 2024	29,674	$ 153.75	8.6	$ —
Options granted	3,200	$ 5.39	9.3	—
Less options forfeited	—	$ —	—	—
Less options expired/cancelled	—	$ —	—	—
Less options exercised	—	$ —	—	—
Options outstanding at December 31, 2024	32,874	$ 139.27	7.8	$ —
Options exercisable at December 31, 2024	29,674	$ 153.71	7.6	$ —

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of $3.02 for the Company's common shares on December 31, 2024 and the closing stock price of $6.80 for the Company's common shares on December 31, 2023.

As of December 31, 2024, the Company had unrecognized stock option expense of approximately $4,000 and have a remaining weighted average period for recognition of 0.27 years.

On March 29, 2023, the Company, pursuant to its 2020 Plan, granted stock options to four Board members to purchase an aggregate of 3,200 shares of common stock. The stock options have an exercise price of $21.75 per share and an expiration date of ten years and vest on the one-year anniversary from the date of the grant. The Company used the Black Scholes valuation method to determine the fair value of the options assuming the following: implied volatility of 123.92%, a risk-free interest rate of 3.66% and have a fair value of $59,763. The options are being expensed over the one-year vesting period from date of issuance.

On April 8, 2024, the Company, pursuant to its 2020 Plan, granted stock options to four Board members to purchase an aggregate of 3,200 shares of common stock. The stock options have an exercise price of $5.39 per share and an expiration date of ten years and vest on the one-year anniversary from the date of the grant. The Company used the Black Scholes valuation method to determine the fair value of the options assuming the following: implied volatility of 124.35%, a risk-free interest rate of 4.43% and have a fair value of $59,763. The options are being expensed over the one-year vesting period from date of issuance.

Director's Compensation Policy

On March 29, 2023, the Company adopted an amended and restated non-employee director compensation policy (the "Director Compensation Policy"). The Director Compensation Policy provides for the annual automatic grant of nonqualified stock options to purchase up to 800 shares of Common Stock to each of the Company's non-employee directors. Such grants shall occur annually on the fifth business day after the filing of our Annual Report on Form 10-K, if available under the Plan, and shall vest on the one-year anniversary from the date of grant, subject to the director's continued service on the Board of Directors on the vesting date. Each newly appointed or elected director will also receive 20,000 options, and such options shall vest 50% on the grant date, 25% on the first anniversary of the grant date and 25% on the second anniversary of the grant date, subject to the director's continued service on the Board of Directors on each vesting date.

The Company recorded total expense of $25,407 and $1,009,325 relating to all outstanding stock options for the year ended December 31, 2024 and 2023, respectively.

Restricted Stock Issuances

On January 8, 2024, the Company issued 14,641 shares of restricted stock to a consultant that was engaged to provide investor relations services with a total fair market value on date of issuance of $100,000, expensed upon issuance. On March 7, 2024, the Company issued 981 shares of restricted stock to a consultant that was engaged to provide investor relations services with a total fair market value on date of issuance of $4,500, expensed upon issuance. On June 7, 2024, the Company issued 1,079 shares of restricted stock to a consultant that was engaged to provide investor relations services with a total fair market value on date of issuance of $4,500, expensed upon issuance. On September 10, 2024, the Company issued 1,304 shares of restricted stock to a consultant that was engaged to provide investor relations services with a total fair market value on date of issuance of $4,500, expensed upon issuance. On December 9, 2024, the Company issued 1,552 shares of restricted stock to a consultant that was engaged to provide investor relations services with a total fair market value on date of issuance of $4,500, expensed upon issuance. On January 9, 2025, the Company issued 30,995 shares of restricted stock to a consultant that was engaged to provide investor relations services with a total fair market value on date of issuance of $100,000, expensed upon issuance. On March 14, 2025, the Company issued 1,655 shares of restricted stock to a consultant that was engaged to provide investor relations services with a total fair market value on date of issuance of $4,502, expensed upon issuance.

Stock Compensation Expense

Total stock-based compensation for the year ended December 31, 2024 was $25,407, of which $0 was classified as research and development expense and $25,407 was classified as general and administrative expense. Total stock-based compensation for the year ended December 31, 2023 was $1,009,325, of which $149,589 was classified as research and development expense and $859,736 was classified as general and administrative expense.

The Company currently estimates, beginning at the closing date of the November 2022 private placement on November 21, 2022, implied volatility factor for all options and warrants based upon a blend of the Parent Company's and Company historical volatility. Up until November 21, 2022, the Company computed implied volatility based upon a blend of the Parent Company's and Company historical volatility along with the volatility of selected comparable publicly traded companies as, at that time, the Company lacks sufficient historical stock trading activity. It incorporated the historical volatility of the Parent company as the Parent company's historical volatility provides a good estimation of the Company's volatility since its operations were identical to the Company's prior to the spin-out.

Note 8 – Common Stock Warrants:

Outstanding Warrants

As of December 31, 2024, the Company had warrants outstanding consisted of the following:

	Number of shares
Warrants outstanding January 1, 2024	287,436
Warrants issued	1,331,431
Warrants expired and canceled	(7,969)
Warrants exercised	—
Warrants outstanding December 31, 2024	1,610,898

As of December 31, 2024, the weighted average exercise price and the weighted average remaining life of the total warrants was $44.14 per warrant and 4.1 years, respectively. The intrinsic value of the warrants as of December 31, 2024 was approximately $92,000.

Note 9 - Fair Value Measurements

Fair value measurements discussed herein are based upon certain market assumptions and pertinent information available to management as of and during the years ended December 31, 2024 and 2023. The carrying amounts of cash equivalents, accounts receivable, other current assets, other assets, accounts payable, and accrued expenses approximated their fair values as of December 31, 2024 and 2023 due to their short-term nature. The fair value of the bifurcated embedded derivative related to the convertible preferred stock was estimated using a Monte Carlo simulation model, which uses as inputs the fair value of our common stock and estimates for the equity volatility and traded volume volatility of our common stock, the time to maturity of the convertible preferred stock, the risk-free interest rate for a period that approximates the time to maturity, dividend rate, a penalty dividend rate, and our probability of default. The fair value of the warrant liability was estimated using the Black Scholes Model which uses as inputs the following weighted average assumptions: dividend yield of 0% and 0%; expected term in years of 2.89 and 3.89; equity volatility of 115% and 115%; and risk-free interest rate of 4.18% and 3.93% for the years ended December 31, 2024 and 2023, respectively.

Fair Value on a Recurring Basis

The Company follows the guidance in ASC 820 for its financial assets and liabilities that are re-measured and reported at fair value at each reporting period, and non-financial assets and liabilities that are re-measured and reported at fair value at least annually. The estimated fair value of the warrant liability and bifurcated embedded derivatives represent Level 3 measurements. The following table presents information about the Company's liabilities that are measured at fair value on a recurring basis at December 31, 2024 and 2023, and indicates the fair value hierarchy of the valuation inputs the Company utilized to determine such fair value:

Description:	Level	December 31 2024	December 31 2023
Assets:			
Convertible note receivable (Note 3)	3	—	$ 1,438,500
Liabilities:			
Warrant liability (Note 6)	3	$ 3,766,000	$ 140,000
Derivative liability (Note 6)	3	$ 6,177,000	$ 1,113,000

The following table sets forth a summary of the change in the fair value of the warrant liability that is measured at fair value on a recurring basis:

	December 31, 2024
Balance on December 31, 2022	$ 1,510,000
Change in fair value of warrant liability	(1,370,000)
Balance on December 31, 2023	$ 140,000
Change in fair value of warrant liabilities Series B Preferred	170,000
Balance of warrant liabilities Series B Preferred	310,000
Warrant liabilities upon issuance of Series C Preferred	2,797,000
Change in fair value of warrant liabilities Series C Preferred	659,000
Balance on December 31, 2024	$ 3,766,000

The following table sets forth a summary of the change in the fair value of the bifurcated embedded derivative liability that is measured at fair value on a recurring basis:

	December 31, 2024
Balance on December 31, 2022	$ 369,400
Change in fair value of bifurcated embedded derivative	(743,600)
Balance on December 31, 2023	$ 1,113,000
Change in fair value of derivative liability Series B Preferred	(1,113,000)
Balance of derivative liability Series B Preferred	—
Derivative liability upon issuance of Series C Preferred	6,096,000
Change in fair value of derivative liability Series C Preferred	81,000
Balance on December 31, 2024	$ 6,177,000

There were no fair value measurements on a non-recurring basis at December 31, 2024 and 2023.

Note 10 – Business Segments:

The Company operates in one business segment, which includes the business of research and development activities related to developing therapeutics for neurodegenerative diseases. The determination of a single business segment is consistent with the financial information regularly provided to the Company's chief operating decision maker ("CODM"). The Company's CODM is its Chief Executive Officer / Chief Medical Officer, in conjunction with its Chairman of the Board and Chief Scientific Officer, who reviews and evaluates net loss for purposes of assessing performance, making operating decisions, allocating resources, and planning and forecasting for future periods.

In addition to the significant expense categories included within net loss presented on the Company's Statements of Operations, see below for disaggregated amounts that comprise research and development expenses:

	Year Ended December 31,	
	2024	2023
External clinical development expenses	$ 1,164,680	$ 1,440,208
Personnel related and stock-based compensation	370,688	462,332
Other research and development expenses	63,354	72,384
Total research and development expenses	$ 1,598,722	$ 1,974,924

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (File No. 333-282589, 333-264325 and 333-268831) and S-8 (333-258807 and 333-268518) of Synaptogenix, Inc., of our report dated April 1, 2024 relating to our audit of the financial statements of Synaptogenix, Inc. as of December 31, 2023 and for the year then ended which appears in this Form 10-K.

/s/ Morison Cogen LLP

Blue Bell, Pennsylvania
March 27, 2025

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (File No. 333-282589, 333-264325 and 333-268831) and S-8 (333-258807 and 333-268518) of Synaptogenix, Inc., of our report dated March 27, 2025 relating to our audit of the financial statements of Synaptogenix, Inc. as of December 31, 2024 and for the year then ended which appears in this Form 10-K.

/s/ Stephano Slack LLC

Wayne, Pennsylvania
March 27, 2025

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

I, Alan J. Tuchman M.D., certify that:

1. I have reviewed this annual report on Form 10-K of Synaptogenix, Inc.;

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

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

4. The registrant's other certifying officer(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:

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

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

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

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

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

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

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

Date: March 27, 2025

By: /s/ Alan J. Tuchman M.D.
Alan J. Tuchman M.D.
Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Robert Weinstein, certify that:

1. I have reviewed this annual report on Form 10-K of Synaptogenix, Inc.;

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

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

4. The registrant's other certifying officer(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:

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

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

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

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

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

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

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

Date: March 27, 2025

By: /s/ ROBERT WEINSTEIN

Robert Weinstein

Chief Financial Officer

(principal financial officer and principal accounting officer)

Exhibit 32.1

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

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Synaptogenix, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended 2024 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 27, 2025 By: /s/ ALAN J. TUCHMAN, M.D.
Alan J. Tuchman, M.D.
Chief Executive Officer
(principal executive officer)

Date: March 27, 2025 By: /s/ ROBERT WEINSTEIN
Robert Weinstein
Chief Financial Officer
(principal financial officer and principal accounting officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.