UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended June 30, 2025

OR

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

Commission File Number 001-41157

Neuphoria Therapeutics Inc.

(Exact name of Registrant as specified in its Charter)

Delaware

Delaware	**99-3845448**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
100 Summit Drive, Burlington, Massachusetts	**01803**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (781) 439-5551

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, $0.00001 par value per share	NEUP	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 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, 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 Exchange Act). YES ☐ NO ☒

The aggregate market value of the Common Stock held by non-affiliates of the registrant was approximately $5,213,998 based on the closing price of the registrant's Common Stock on December 31, 2024, the last business day of the registrant's most recently completed second fiscal quarter.

The number of shares of Registrant's Common Stock outstanding as of September 29, 2025 was 2,357,613.

DOCUMENTS INCORPORATED BY REFERENCE

List hereunder the following documents if incorporated by reference and the Part of the Form 10-K (e.g., Part I, Part II, etc.) into which the document is incorporated: (1) Any annual report to security holders; (2) Any proxy or information statement; and (3) Any prospectus filed pursuant to Rule 424(b) or (c) under the Securities Act of 1933. The listed documents should be clearly described for identification purposes (e.g., annual report to security holders for fiscal year ended December 24, 1980).

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Basis of Presentation

Neuphoria Therapeutics Inc. is a Delaware corporation ("Neuphoria") listed on the Nasdaq Global Market. We were formally known as Bionomics Limited ("Bionomics") an Australian company that on October 1, 2024 entered into a Scheme Implementation Agreement with Neuphoria to re-domicile from Australia to the State of Delaware pursuant to a Scheme of Arrangement under Australian law. On December 23, 2024, the re-domiciliation of Bionomics was implemented and effectuated in accordance with the Scheme Implementation Agreement, as amended. As a result, (i) holders of ordinary shares of Bionomics received one share of our common stock for every 2,160 ordinary shares of Bionomics held on the Scheme record date; (ii) holders of Bionomics' American Depositary Shares ("ADS") with each ADS representing 180 ordinary shares of Bionomics, received one share of Neuphoria's common stock for every 12 ADSs held on the Scheme record date; and (iii) we became the successor issuer to Bionomics. Prior to our redomiciliation, since July 1, 2024, we had been reporting as a domestic U.S. issuer on SEC Forms 10-K, 10-Q, and 8-K.

The terms "we," "our," "us" and the "Company" in this Annual Report on Form 10-K refer to Neuphoria Therapeutics Inc. and its consolidated subsidiaries after December 23, 2024 and Bionomics and its consolidated subsidiaries on and prior to December 23, 2024, unless otherwise specified. When we refer to "you," we mean the potential holders of the applicable series of securities:

- "shares" or "ordinary shares" refers to our ordinary shares prior to December 23, 2024;
- "shares of common stock" refers to our common stock, par value $0.00001 per share beginning December 24, 2024;
- "ADSs" refers to American Depositary Shares, each of which represented 180 ordinary shares prior to December 23, 2024; and
- "ADRs" refers to American Depositary Receipts, which evidence the ADSs.

We use our registered and unregistered trademarks, including Neuphoria™ and Bionomics™, in this Annual Report on Form 10-K (the "Annual Report"). This Annual Report also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this Annual Report appear without the ®and ™ symbols, but those references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

All references to "$" and "US$" in this Annual Report mean U.S. dollars. All references to "A$" in this Annual Report mean Australian dollars.

Our fiscal year end is June 30. References to a particular "fiscal year" are to our fiscal year ended June 30 of that calendar year.

Unless otherwise indicated, the consolidated financial statements and related notes incorporated in this Annual Report on Form 10-K have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") and are presented in U.S. dollars.

Certain monetary amounts, percentages and other figures included herein have been subject to rounding adjustments. Accordingly, figures shown as totals in certain tables and charts may not be the arithmetic aggregation of the figures that precede them, and figures expressed as percentages in the text may not total 100% or, as applicable, when aggregated may not be the arithmetic aggregation of the percentages that precede them.

Cautionary Note Regarding Forward-Looking Statements

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "estimate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions intended to identify statements about the future. These statements speak only as of the date of filing this report with the Securities and Exchange Commission (the "SEC") and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These forward-looking statements include, without limitation, statements about the following:

- our lack of operating history and need for additional capital;
- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates and other positive results;
- the timing and focus of our clinical trials and preclinical studies, and the reporting of data from those trials and studies;
- our plans relating to commercializing any product candidates, including the geographic areas of focus and sales strategy;
- the market opportunity and competitive landscape for our product candidates, including our estimates of the number of patients who suffer from the conditions we are targeting;

- the success of competing therapies that are or may become available;
- our estimates of the number of patients that we will enroll in our clinical trials;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates;
- the timing of initiation and completion, and the progress of our drug discovery and research programs;
- the timing or likelihood of regulatory filings and approvals for our product candidates for various diseases;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our plans relating to the development of our product candidates, including additional indications we may pursue;
- existing regulations and regulatory developments in the United States, Australia, Europe and other jurisdictions;
- our plans and ability to obtain, maintain, protect and enforce our intellectual property rights and our proprietary technologies, including extensions of existing patent terms where available;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials;
- our plans regarding any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- our estimates regarding expenses, future revenue, capital requirements, and the impact of a fluctuating currency exchange on these estimates;
- our financial performance;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;
- our anticipated use of our existing resources;
- cyber security risks and any failure to maintain the confidentiality, integrity and availability of our computer hardware, software and internet applications and related tools and functions; and
- other risks and uncertainties, including those listed under "Risk Factors."

The forward-looking statements contained in this Annual Report on Form 10-K are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described under the section of this Annual Report entitled "*Risk Factors*." Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

Although we believe that the assumptions on which these forward-looking statements are based are reasonable, any of those assumptions could prove to be inaccurate, and as a result, the forward-looking statements based on those assumptions also could be inaccurate. In light of these and other uncertainties, the inclusion of a projection or forward-looking statements in this Annual Report should not be regarded as a representation by us that our plans and objectives will be achieved.

We have based the forward-looking statements included in this Annual Report on information available to us on the date of this Annual Report, and we assume no obligation to update any such forward-looking statements. Although we undertake no obligation to revise or update any forward-looking statements in this Annual Report, whether as a result of new information, future events or otherwise, you are advised to consult any additional disclosures that we may make directly to you or through reports that we may file in the future with the Securities and Exchange Commission ("SEC") including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K.

PART I

Item 1. Business.

Overview

We are a clinical-stage biotechnology company dedicated to developing therapies that address the complex needs of individuals affected by neuropsychiatric disorders. Neuphoria is advancing its lead drug candidate, BNC210, an oral, proprietary, selective negative allosteric modulator of the α7 nicotinic acetylcholine ("ACh") receptor ("a7 receptor") for the acute, “as needed” treatment of social anxiety disorder (“SAD”) and for chronic treatment of post-traumatic stress disorder (“PTSD”). There remains a significant unmet medical need for the over 27 million patients in the United States alone suffering from SAD and PTSD. BNC210 is a first-of-its-kind, well-tolerated, broad spectrum anti-anxiety experimental therapeutic, designed to restore neurotransmitter balance in relevant brain areas, providing rapid relief from stress and anxiety symptoms without the common pitfalls of sedation, cognitive impairment, or addiction. In addition, Neuphoria has a strategic partnership with Merck & Co., Inc., known as Merck outside the United States and Canada, with two drugs in early-stage clinical trials for the treatment of cognitive deficits in Alzheimer’s disease and other central nervous system ("CNS") conditions. Neuphoria's pipeline also includes the α7 nicotinic acetylcholine receptor next generation and the Kv3.1/3.2 preclinical programs, both in the lead optimization development stage.

Current pharmacological treatments include certain antidepressants and benzodiazepines, and there have been no new Food and Drug Administration ("FDA") approved therapies in these indications in nearly two decades. These existing treatments have multiple shortcomings, such as a slow onset of action of antidepressants, and significant side effects of both classes of drugs, including abuse liability, addiction potential and withdrawal symptoms. BNC210 has been observed in our clinical trials to have a fast onset of action and clinical activity without the limiting side effects seen with the current standard of care.

In December 2022, we announced the results of the Phase 2 PREVAIL trial for BNC210 for the acute treatment of SAD. While PREVAIL missed its primary endpoint, as measured by the change from baseline to the average of the Subjective Units of Distress Scale (“SUDS”) scores during a 5-minute Public Speaking Challenge in the BNC210-treated patients when compared to placebo, the data readout revealed encouraging trends in the prespecified endpoints. The findings did indicate a consistent trend toward improvements across primary and secondary endpoints and a favorable safety and tolerability profile consistent with previously reported results. These results supported a post-hoc in-depth analysis of the full dataset to better understand the potential of the drug and guide late-stage trial design. In October 2023, we announced a positive outcome of an End-of-Phase 2 meeting with FDA that enabled advancement of BNC210 into Phase 3 studies in SAD. In July 2024, we announced the initiation of patient screening for the Phase 3 AFFIRM-1 trial evaluating the safety and efficacy of BNC210 for the acute, as-needed treatment of SAD. AFFIRM-1 targets enrollment of approximately 332 adult patients with SAD at clinical sites in the United States. It is a multi-center, double-blind, two-arm, parallel group, placebo-controlled trial. Participants will be randomized 1:1 to receive a single dose of 225 mg BNC210 or matched placebo about one hour before speaking in public. The primary endpoint will compare BNC210 to placebo using the SUDS to measure self-reported anxiety levels during the performance of a public speaking task. Secondary efficacy endpoints include the SUDS to measure self-reported anxiety levels in anticipation of a public speaking task, the Clinical and Patient Global Impression (“CGI” and “PGI”, respectively) scales and the State-Trait Anxiety Inventory (“STAI”). As discussed with the FDA during the program’s End-of-Phase 2 meeting, AFFIRM-1 is the first of two placebo-controlled trials required to enable a New Drug Application (“NDA”) submission. Topline results from the AFFIRM-1 trial are expected early in the fourth quarter of calendar 2025. We plan to initiate the AFFIRM-2 trial in SAD in the first half of 2026, contingent upon successful outcomes of AFFIRM-1 and having sufficient capital on hand.

In September 2023, we announced the results of the Phase 2b ATTUNE trial, which was a double-blind, placebo-controlled trial conducted in a total of 34 sites in the United States and the United Kingdom, with 212 enrolled patients, randomized 1:1 to receive either twice daily 900 mg BNC210 as a monotherapy (n=106) or placebo (n=106) for 12 weeks. The trial met its primary endpoint of change in Clinician-Administered PTSD Scale for DSM-5 (“CAPS-5”) total symptom severity score from baseline to Week 12 (p=0.048). A statistically significant change in CAPS-5 score was also observed at Week 4 (p=0.016) and at Week 8 (p=0.015). Treatment with BNC210 also showed statistically significant improvement both in clinician-administered and patient self-reporting in two of the secondary endpoints of the trial. Specifically, BNC210 led to significant improvements at Week 12 in depressive symptoms (p=0.041) and sleep (p=0.039) as measured by Montgomery-Åsberg Depression Rating Scale (“MADRS”) and Insomnia Severity Index (ISI), respectively. BNC210 also showed signals and trends across visits in the other secondary endpoints including the clinician and patient global impression - symptom severity (“CGI-S”, “PGI-S”, respectively) scales and the Sheehan Disability Scale (“SDS”). In July 2024, we announced a positive outcome of an End-of-Phase 2 meeting with FDA that provides a potential path to NDA submission for BNC210 for PTSD that alongside the positive Phase 2b ATTUNE trial includes a single additional registrational trial. Start-up activities for a planned Phase 2b/3 trial of BNC210 in PTSD are underway. We plan to initiate the Phase 2b/3 SYMPHONY trial in PTSD in the first half of 2026, contingent upon having sufficient capital on hand.

The Company's expertise in ion channels and approach to developing allosteric modulators have been validated through its strategic partnership with Merck for our α7 receptor positive allosteric modulator ("PAM") program, which targets a receptor that has garnered significant attention for treating cognitive deficits. This partnership enables Neuphoria to maximize the value of its ion channel and chemistry platforms and develop transformative medicines for patients suffering from cognitive disorders such as Alzheimer's disease.

On March 19, 2025, the Company received a $15 million milestone payment from Merck. The payment was triggered by the initiation by Merck of a Phase 2 clinical trial to evaluate the safety and efficacy of MK-1167, an α7 receptor PAM, for the treatment of the symptoms of Alzheimer's disease dementia (NCT06721156). This $15 million payment marks the third milestone achieved in the collaboration with Merck. Under the agreement Neuphoria is eligible to receive up to $450 million in additional research and commercial milestone payments for certain development and commercial milestones associated with the progress of multiple candidates, plus royalties on net sales of any licensed medicines.

In November 2020, we entered into an intellectual property ("IP") license agreement (the "Carina Biotech License") with Carina Biotech ("Carina"). Pursuant to the Carina Biotech License, we are eligible to receive up to A$118 million in certain development, regulatory and commercial milestone payments if Carina fully develops and markets the new therapy. Carina is also obligated to pay us royalties on its net sales of licensed products, on a country-by-country and product-by-product basis, ranging from the low single digits to the mid-single digits, subject to certain specified deductions. On October 30, 2024, Carina made a milestone payment to the Company in the gross amount of A$1 million under the terms of the Carina Biotech License agreement. The milestone payment was due to the Company as Carina achieved the initiation (i.e., first dosing in a human subject) of the first Phase 1 Clinical Trial with next-generation LGR5 stem cell antigen CAR-T technology (CNA3103) targeting solid tumors.

Below is a summary of our pipeline:

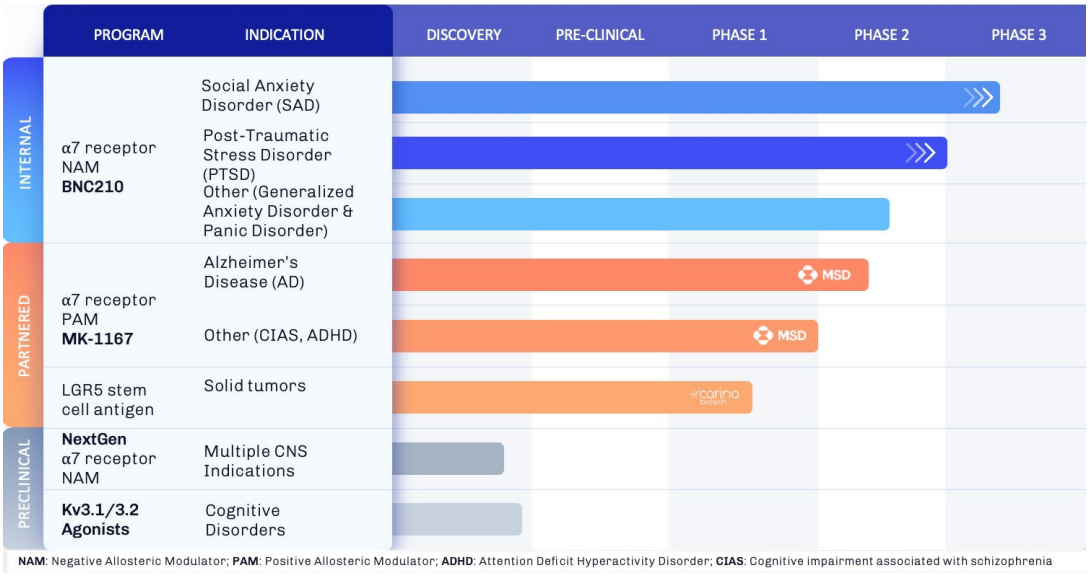

Figure 1: Neuphoria's development pipeline.

BNC210

We are initially focused on developing BNC210 for two distinct indications with high unmet medical need: (i) acute treatment of SAD and (ii) chronic treatment of PTSD. In our clinical trials to-date, BNC210 has been observed to have a fast onset of action, and demonstrated clinical anti-anxiety and anti-depressive activity, but without many of the limiting side effects observed with the current standards of care for SAD and PTSD, including benzodiazepines, selective serotonin reuptake inhibitors ("SSRIs") and serotonin and norepinephrine reuptake inhibitors ("SNRIs"). Based on extensive preclinical data and clinical trials, we believe BNC210 may have a number of advantages over drugs currently used to treat anxiety, depression and PTSD, including:

- Fast acting anxiolytic with the potential to be used in both acute and chronic settings;
- non-sedating;

- no addictive effect and a lack of discontinuation/withdrawal syndrome;
- no memory impairment;
- no impairment of motor coordination; and
- no suicidality liability.

We have administered BNC210 to approximately 790 subjects across 15 clinical trials, including healthy volunteers, elderly patients with agitation and patients with Generalized Anxiety Disorder ("GAD"), SAD and PTSD. We have observed BNC210 to be generally well tolerated in the trials to date following both acute and chronic dosing.

Further, in our clinical trials in GAD patients and in panic-induced healthy subjects, we have observed three key results:

- statistically significant reductions in hyperactivity in the amygdala, the region of the brain responsible for emotional control, when exposed to fear-inducing triggers;
- in a head-to-head study, showed a statistically significant reduction in the intensity of defensive behavior, while lorazepam, a widely prescribed benzodiazepine did not; and
- a statistically significant reduction in the intensity and total number of panic symptoms.

We have designed and developed a novel, proprietary tablet formulation of BNC210 which has shown differentiated pharmacokinetic properties in clinical trials. BNC210 tablet has demonstrated rapid oral absorption characteristics in clinical trials making it ideal for acute, or on demand, treatment of SAD. Furthermore, the tablet formulation is intended to provide patients the convenience of taking BNC210 with or without food in the outpatient setting and strengthen the BNC210 IP portfolio.

In December 2022, we announced the results of the Phase 2 PREVAIL trial for BNC210 for the acute treatment of SAD. While PREVAIL narrowly missed its primary endpoint, as measured by the change from baseline to the average of the SUDS scores during a 5-minute Public Speaking Challenge in the BNC210-treated patients when compared to placebo, the data readout revealed encouraging trends in the prespecified endpoints that focused on individual phases of the public speaking task. The findings did indicate a consistent trend toward improvements across primary and secondary endpoints and a favorable safety and tolerability profile consistent with previously reported results. The results of the Phase 2 PREVAIL trial were published in the Psychiatry Research in early 2025 (Papapetropoulos S, et al. Psychiatry Research, Volume 346, 2025).

We also completed an FDA End-of-Phase 2 meeting to discuss the registrational program for BNC210 in SAD.

In October 2023, the Company received the official meeting minutes from the End-of-Phase 2 meeting with the FDA held on September 13, 2023 reflecting that the Company has reached an agreement with the FDA on the following:

- the plan to conduct two single dose randomized, placebo-controlled studies;
- the use of the SUDS measured during a public speaking challenge as the primary efficacy endpoint;
- the doses of BNC210 to be studied in Phase 3;
- the sample size assumptions for the Phase 3 controlled studies based on PREVAIL findings;
- the design elements of the open label safety study;
- the size of the safety database to support the NDA; and
- the nonclinical toxicology studies needed to support the NDA.

In July 2024, we announced the initiation of patient screening for the Phase 3 AFFIRM-1 trial evaluating the safety and efficacy of BNC210 for the acute, as-needed treatment of SAD. AFFIRM-1 targets enrollment of approximately 332 adult patients with SAD at clinical sites in the United States. It is a multi-center, double-blind, two-arm, parallel group, placebo-controlled trial. Participants will be randomized 1:1 to receive a single dose of 225 mg BNC210 or matched placebo about one hour before speaking in public. The primary endpoint will compare BNC210 to placebo using the SUDS to measure self-reported anxiety levels during a public speaking task. Secondary efficacy endpoints include the CGI and PGI scales and STAI. Topline results from the AFFIRM-1 trial are expected in the fourth quarter of 2025. We plan to initiate the AFFIRM-2 trial in SAD in the first half of 2026, contingent upon successful outcomes of AFFIRM-1 and having sufficient capital on hand.

In September 2023, we announced the results of the Phase 2b ATTUNE trial, which was a double-blind, placebo-controlled trial conducted in a total of 34 sites in the United States and the United Kingdom, with 212 enrolled patients, randomized 1:1 to receive either twice daily 900 mg BNC210 as a monotherapy (n=106) or placebo (n=106) for 12 weeks. The trial met its primary endpoint of

change in CAPS-5 total symptom severity score from baseline to Week 12 (p=0.048). A statistically significant change in CAPS-5 score was also observed at Week 4 (p=0.016) and at Week 8 (p=0.015). Treatment with BNC210 also showed statistically significant improvement both in clinician-administered and patient self-reporting in two of the secondary endpoints of the trial. Specifically, BNC210 led to significant improvements at Week 12 in depressive symptoms (p=0.041) and sleep (p=0.039) as measured by MADRS and ISI, respectively. BNC210 also showed signals and trends across visits in the other secondary endpoints including the CGI-S, PGI-S and the SDS.

In July 2024, we announced a positive outcome of an End-of-Phase 2 meeting with the FDA. the Company presented the clinical plans to registration, that alongside the positive Phase 2b ATTUNE trial, include a single additional placebo-controlled registrational trial with a 52-week open-label extension. The meeting, held on June 26, 2024, was centered around the design of this trial that if successful may enable review of the NDA submission. Key outcomes from the discussion on the trial design included:

- Agreement was reached on the use of CAPS-5 as the primary endpoint measure and the CGI-S as a key secondary endpoint measure in the placebo-controlled part of the study.
- Agreement was reached that in addition to the efficacious dose of 900 mg twice daily, a lower dose of BNC210 will be tested that strikes the right balance between maintenance of efficacy and safety related to liver function tests ("LFT") findings observed in ATTUNE.
- High-level agreement was reached on study participant characteristics and sample size assumption methodology.
- The Company received guidance related to the proposed hepatic safety monitoring plan, including monitoring for excessive alcohol use that will be implemented in the planned Phase 2b/3 trial.

Contingent upon having sufficient capital on hand, we anticipates beginning the Phase 2b/3 program in PTSD in the first half of calendar 2026.

We have received Fast Track designation from the FDA for our PTSD and SAD programs.

Additional Programs

α7 Receptor PAM Program with Merck

In June 2014, we entered into a License Agreement with Merck to develop α7 receptor PAMs targeting cognitive dysfunction associated with Alzheimer's disease and other central nervous system conditions. Under the 2014 License Agreement, Merck funded certain research and development activities on a full-time equivalent ("FTE") basis pursuant to a research plan. Merck funds current and future research and development activities, including clinical development and worldwide commercialization of any products developed from the collaboration. The Merck collaboration currently includes two clinical stage candidates which are PAMs of the α7 receptor (MK4334 and MK-1167) that are being developed for treating cognitive impairment in various CNS disorders.

We received upfront payments totaling $20 million, which included funding for FTEs for the first twelve months, and another $10 million in February 2017 when the first compound from the collaboration-initiated Phase 1 clinical trials. On March 19, 2025, the Company received a $15 million milestone payment from Merck. The payment was triggered by the initiation by Merck of a Phase 2 clinical trial to evaluate the safety and efficacy of MK-1167, an α7 nicotinic acetylcholine receptor PAM, for the treatment of the symptoms of Alzheimer's disease dementia (NCT06721156). This $15 million payment marks the third milestone achieved in the collaboration with Merck. Under the agreement, as amended, Neuphoria is eligible to receive up to $450 million in additional research and commercial milestone payments for certain development and commercial milestones associated with the progress of multiple candidates, plus royalties on net sales of any licensed medicines.

Merck controls the clinical development and worldwide commercialization of any products developed from the collaboration and therefore we cannot predict whether or when we might achieve any milestone payments under the collaboration or estimate the full amount of such payments, and we may never receive any such payments. Further, we are subject to limited information rights under the 2014 Merck License Agreement. As such, we are dependent on Merck to provide us with any updates related to clinical trial results, serious adverse events and ongoing communications with FDA or other regulatory agencies related to these programs, which Merck may provide or withhold in its sole discretion, and as a result we may not be able to provide material updates on a timely basis or at all with respect to these programs.

The Company evaluated the Merck Agreement in accordance with the provisions of Accounting Standards Codification Topic 606, Revenue from Contracts with Customers ("ASC 606"). The Company's obligation under the Merck Agreement related to the residual variable consideration associated with the Merck Agreement are as follows: the Company granted to Merck an exclusive license (even as to the Company and its Affiliates) in the Territory under the Bionomics Ltd. Patent Rights and Bionomics Ltd. know-how, with a

right to grant and authorize sublicenses, to research, develop, make, have made, use, offer to sell, sell, import and/or otherwise exploit compounds and products in the field.

Regulatory milestone payments are triggered upon the achievement of certain research and commercial milestones. The commercial milestone payments and royalties are subject to the royalty recognition constraint whereby such amounts will be recognized as revenue upon the later of: (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the payment has been allocated has been satisfied, or partially satisfied, because the exclusive license is deemed to be the sole or predominant item to which the payments relate. As all performance obligations are satisfied, the Company will recognize royalty revenue at the date the sales occur.

On March 14, 2025, the Company and Merck executed the Fifth Amendment to the Research Collaboration and License Agreement which amended the patent royalty rate set out in the Agreement, such that, conditioned upon achievement of net sales thresholds set forth in the Merck Agreement, as amended, the Company will be paid royalties on net sales ranging from a low single digits percentage to a low sub-teens percentage, depending on net sales volume. There were no other changes in the transaction price during the twelve months ended June 30, 2025.

Our Early-Stage CNS Assets

Our CNS pipeline includes two earlier stage small molecule discovery programs targeting ion channels and represents additional opportunities for future clinical programs and partnering.

Utilizing our expertise in ion channel biology and translational medicine, we developed next generation patented orally bioavailable small molecule series of NAM targeting α7 nicotinic acetylcholine receptor that can be potentially positioned for the treatment of CNS disorders of high unmet clinical need. We are also continuing development of our lead series Kv3.1/3.2 potassium channel activators for the potential treatment of cognitive deficits and negative symptoms/social withdrawal in schizophrenia and autism spectrum disorders. We plan to advance our early-stage programs either internally or through potentially new partnerships.

We plan to advance our early-stage programs either internally or through potentially new partnerships.

Legacy Oncology Programs

We have a portfolio of legacy clinical-stage oncology programs targeting cancer stem cells (BNC101) and tumor vasculature (BNC105) that we have progressed through external funding for clinical trials and out-licensing to capture future value for our shareholders. Our first legacy oncology program is BNC101, a novel humanized monoclonal antibody that targets LGR5, a cancer stem cell receptor highly overexpressed in most solid tumors. In November 2020, we exclusively licensed BNC101 to Carina for the development of chimeric receptor antigen T-cell ("CAR-T") therapeutics. Pursuant to the Carina Biotech License, we are eligible to receive up to $75.8 million in certain development, regulatory and commercial milestone payments if Carina fully develops and markets the new therapy. Carina is also obligated to pay us royalties on its net sales of licensed products, on a country-by-country and product-by-product basis, ranging from the low single digits to the mid-single digits, subject to certain specified deductions. In January 2023, Carina announced that it had received an FDA "Safe to Proceed" Letter for a Phase 1/2a clinical trial of BNC101 CAR-T therapy for the treatment of advanced colorectal cancer. In December 2023, Carina announced that patient dosing for their Phase 1/2a study had commenced. On October 30, 2024, Carina made a milestone payment to the Company in the gross amount of A$1 million under the terms of the Carina Biotech License agreement. The milestone payment was due to the Company as Carina achieved the initiation (i.e., first dosing in a human subject) of the first Phase 1 Clinical Trial with next-generation LGR5 stem cell antigen CAR-T technology (CNA3103) targeting solid tumors.

Our second legacy oncology program, BNC105, is a novel vascular tubulin polymerization inhibitor agent for treatment of cancer, which disrupts the blood vessels that nourish tumors. We plan to advance these oncology programs only through existing and potentially new partnerships.

Our Strategy

Our goal is to be a leading biopharmaceutical company focused on the development and commercialization of novel treatments to transform the lives of patients with serious CNS disorders with high unmet medical need. The key elements of our strategy include:

- Advancing our lead product candidate, BNC210, through clinical development and to commercialization, if approved, for the acute treatment of patients with SAD. Based on the favorable rapid absorption profile of our novel tablet formulation and evidence of anti-anxiety effect from our prior Phase 1b panic attack trial and our Phase 2 GAD trial, we believe there is a strong clinical and translational rationale to advance BNC210 for the acute treatment of patients with SAD, which we believe now has a defined clinical and regulatory pathway based on the positive outcome of the End-of-Phase 2 meeting with the FDA in September 2023 that enabled advancement of BNC210 into Phase 3 in SAD. While PREVAIL narrowly

missed its primary endpoint, as measured by the change from baseline to the average of the SUDS scores during a 5-minute Public Speaking Challenge in the BNC210-treated patients when compared to placebo, the December 2022 topline data readout revealed encouraging trends in the prespecified endpoints that focused on individual phases of the public speaking task and clinically meaningful anxiolytic treatment effects that are comparable to the treatment effects seen with frequently used benzodiazepines such as diazepam in a clinical study with a similar design to PREVAIL. The findings indicated a consistent trend toward improvements across primary and secondary endpoints and a placebo-like safety and tolerability profile with the 225 mg dose consistent with previously reported results. In July 2024, we announced the initiation of patient screening for the Phase 3 AFFIRM-1 trial evaluating the safety and efficacy of BNC210 for the acute, as-needed treatment of SAD. AFFIRM-1 targets enrollment of approximately 332 adult patients with SAD at clinical sites in the United States. It is a multi-center, double-blind, two-arm, parallel group, placebo-controlled trial. Participants will be randomized 1:1 to receive a single dose of 225 mg BNC210 or matched placebo about one hour before speaking in public. The primary endpoint will compare BNC210 to placebo using the SUDS to measure self-reported anxiety levels during a public speaking task. Secondary efficacy endpoints include the CGI and PGI scales and the STAI. Topline results from the AFFIRM-1 trial are expected early in the fourth quarter of calendar 2025.

•Advancing our lead product candidate, BNC210 through clinical development and to commercialization, if approved, in patients with PTSD. BNC210 is an oral, proprietary, selective NAM of the α7 receptor designed to normalize the neurotransmitter imbalance and address anxiety and stressor-related disorders. In September 2023, we announced the results of the Phase 2b ATTUNE study which was a double-blind, placebo-controlled trial conducted in a total of 34 sites in the United States and the United Kingdom, with 212 enrolled patients, randomized 1:1 to receive either twice daily 900 mg BNC210 as a monotherapy (n=106) or placebo (n=106) for 12 weeks. The trial met its primary endpoint of change in CAPS-5 total symptom severity score from baseline to Week 12 (p=0.048). A statistically significant change in CAPS-5 score was also observed at Week 4 (p=0.016) and at Week 8 (p=0.015). Treatment with BNC210 also showed statistically significant improvement both in clinician-administered and patient self-reporting in two of the secondary endpoints of the trial. Specifically, BNC210 led to significant improvements at Week 12 in depressive symptoms (p=0.041) and sleep (p=0.039) as measured by MADRS and ISI, respectively. BNC210 also showed signals and trends across visits in the other secondary endpoints including the CGI-S, PGI-S and SDS. Contingent upon successful capital raise, we are planning to initiate a Phase 2b/3 study in PTSD in the first half of calendar 2026.

•Expand indication potential for BNC210 to other acute and chronic CNS disorders. Based on what we believe is the novel mechanism of action of BNC210, data observed in approximately 790 subjects to date in 15 clinical trials that BNC210 has been generally well tolerated, and the broad utility of NAMs of the α7 receptor, we believe BNC210 has the potential to address a wide range of CNS disorders beyond acute treatment of SAD and chronic treatment of PTSD. We intend to continue evaluating BNC210's potential for acute and chronic treatment of additional anxiety indications such as GAD, panic disorder and chronic treatment of SAD.

•Build a commercialization infrastructure in the United States for BNC210 to maximize its commercial opportunity across global markets. We currently intend to build a focused commercial organization in the United States to market BNC210, if approved. Outside the United States, we will evaluate strategic opportunities to maximize the commercial potential of BNC210 with collaborators whose development and commercial capabilities complement our own.

•Maximize the potential of our preclinical CNS programs and legacy oncology assets through selective partnerships and licensing. We have generated a series of product candidates that may have transformative potential across a range of CNS indications through our expertise in ion channels and, specifically, α7 receptors including a next generation α7 receptor NAM series. We have an ongoing collaboration with Merck for our α7 receptor PAM program to treat patients with cognitive impairment associated with Alzheimer's disease and other CNS conditions. We have also used our expertise in ion channel biology to identify Kv3.1/3.2 activators with transformative potential for patients suffering from cognitive disorders which we plan to leverage for future partnerships or licensing. In addition, we expect to continue to advance our legacy oncology programs through existing and future external funding and out-licensing to capture potential value for our shareholders.

•Continue to strategically expand our clinical pipeline through acquisitions, licenses, and/or collaborations. We intend to take advantage of our management team's substantial expertise in translational medicine and clinical development of drugs for psychiatric and neurological disorders to opportunistically identify and in-license or acquire additional clinical-stage innovative therapies for diseases within CNS.

Background and Rationale on Targeting Ion Channels for CNS Disorders

Overview of Ion Channels as a Drug Class

Ion channels facilitate the movement of charged molecules across cellular membranes and are responsible for electrical signaling, serving as important mediators of physiological functions in the CNS. Modulation of ion channels influences neurotransmission that

leads to downstream signaling in the brain. While ion channels are commonly implicated in disease, due to the complexity of ion channels and limitations in drug discovery, only a small percentage of the ion channels implicated in these diseases have drugs available to treat the disorders. Therefore, we believe that ion channels represent a significant untapped domain for future drug development across a variety of neuropsychiatric and neurological disorders.

Hypercholinergic and Hypocholinergic Disease States

ACh is a neurotransmitter and neuromodulator involved in signaling in the CNS. ACh serves a number of critical functions, which can be impaired by diseases that influence ACh levels in the body. When levels of ACh are elevated in critical regions of the brain, the result is a "hypercholinergic disease state", whereas when levels of ACh are inadequate in critical regions of the brain, the result is a "hypocholinergic disease state" (Figure 2). Neuphoria is initially seeking to treat conditions of hypercholinergic and hypocholinergic disease states using therapeutics that restore homeostasis.

α7 Nicotinic Acetylcholine Receptor as a Target

The α7 receptor is a member of the cys-loop, ligand-gated, ion channel superfamily, which includes several other nicotinic receptor subtypes as well as GABA-A, glycine and 5-HT3 receptors. The α7 receptor is unique because of its high calcium ion ("Ca^{2+}") permeability and rapid desensitization. It is highly expressed in brain regions associated with cognitive performance, such as the basal forebrain, hippocampus and prefrontal cortex, as well as regions associated with emotional control, such as the amygdala and hippocampus. When the ACh neurotransmitter binds to the α7 receptor, the ion channel opens and preferentially allows calcium ions to flow into the cell. These calcium ions act as secondary messengers and trigger signaling cascades, including release of additional neurotransmitters, that contribute to the important CNS modulatory role of this receptor.

Dysfunction of the α7 receptor and altered levels of ACh have been associated with a broad array of neuropsychiatric and neurologic disorders such as SAD, GAD, PTSD, Cognitive Impairment Associated with Schizophrenia ("CIAS"), Attention Deficit Hyperactivity Disorder ("ADHD") and Alzheimer's disease. Excess levels of ACh in brain regions involved in emotional control, such as the amygdala and the neocortex, can cause symptoms of anxiety and depression. While stress-induced ACh release can facilitate normal adaptive responses to environmental stimuli, known as fight or flight, chronic elevations of ACh signaling may produce maladaptive behaviors culminating in anxiety and stressor-related disorders such as SAD, GAD and PTSD. Conversely, low levels of ACh resulting from loss of cholinergic neurons in brain regions such as the basal forebrain and hippocampus contribute to cognitive deficits in Alzheimer's disease (Figure 2).

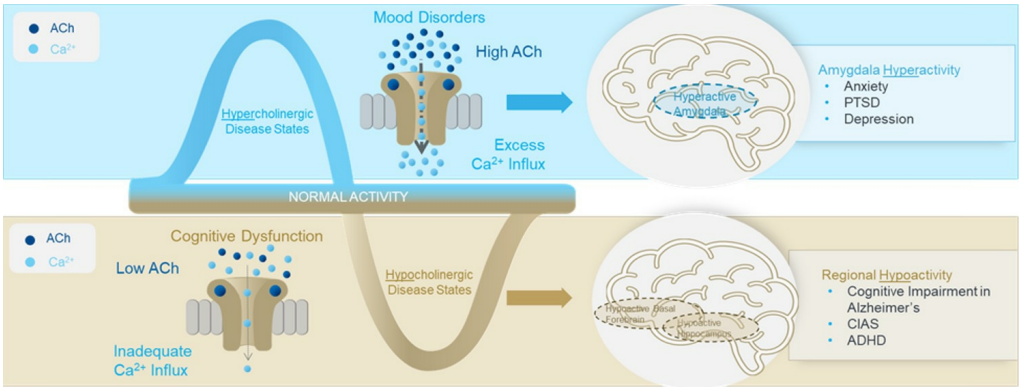

Figure 2: CNS conditions with acetylcholine imbalance at the α7 receptor.

Our Approach: Allosteric Modulation of the α7 Receptor and Clinical Biomarkers

We are focused on advancing a pipeline of both NAMs and PAMs of the α7 receptor to treat anxiety-related and cognitive disorders, respectively. Allosteric sites found on ion channels are distinct from orthosteric sites where active substrates, such as ACh, choline and nicotine bind. The α7 receptor is made up of five identical alpha subunits spanning the neuronal membrane, providing five orthosteric agonist binding sites. In response to ACh, the opening and closing of the ion channel allows the preferential flow of Ca2+ into the cell, which governs neuronal function and neurotransmission, as seen in the figure below.

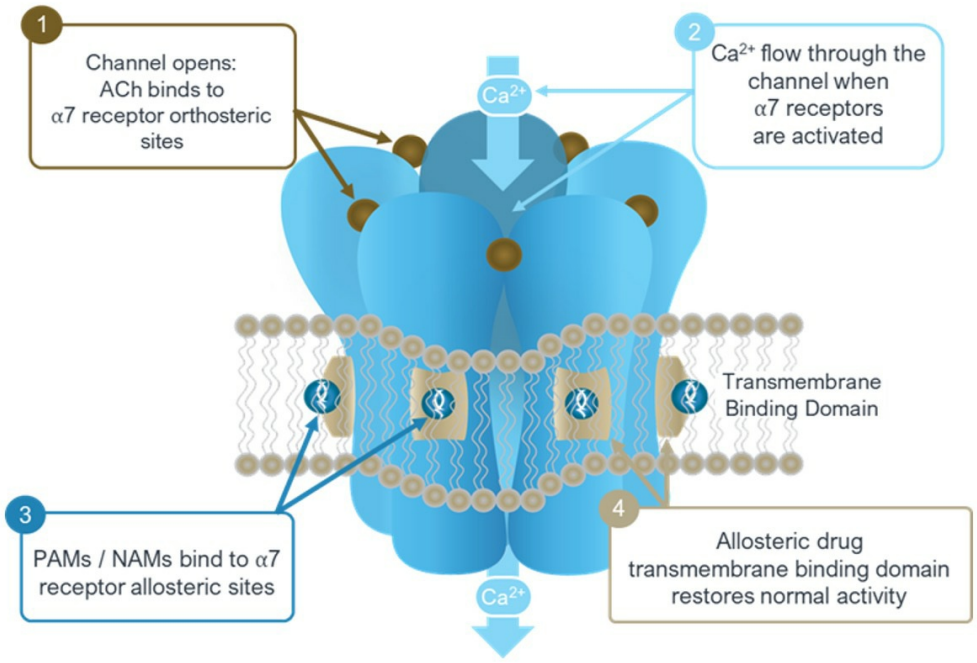

Figure 3: Structure of the α7 receptor showing the orthosteric and allosteric binding sites.

The α7 receptor has garnered significant attention as a target for cognitive deficits based on receptor localization, and because of robust effects observed in preclinical studies and genetic implication of its involvement in cognitive disorders. Historically, therapeutics that modulate the α7 receptor have either targeted the orthosteric agonist sites or blocked the channel. These conventional orthosteric α7 receptor agonists have suffered from off-target activity, receptor desensitization, and a narrow therapeutic window that have limited their clinical utility. Allosteric modulators of the α7 receptor bind at the transmembrane region (see Figure 3) at sites distinct from the orthosteric sites. Allosteric modulators on their own have no effect on the receptor and act only when agonists, such as ACh, nicotine or choline, are bound to the orthosteric site. Binding to allosteric sites on the α7 receptor can diminish or enhance the effects of orthosteric agonist binding. Through the dynamic interaction between the molecules bound to each site, allosteric modulators serve to "normalize" function of the ion channel by mitigating hypercholinergic and hypocholinergic disease states (see Figure 3). As such, allosteric modulators have several potential key advantages, including potentially improved safety profiles and lower likelihood of desensitization, resulting in potentially greater efficacy, as compared to historically used orthosteric agonists or channel blockers.

We have utilized our expertise in ion channel biology to identify orally active, highly selective small molecule α7 receptor allosteric modulators designed to penetrate the blood-brain barrier and overcome the limitations associated with orthosteric agonists or channel blockers.

Beyond the discovery phase, our clinical development strategy is strengthened by using an array of established and well-defined translational tools, including well-established biomarkers. We leverage biomarkers, functional magnetic resonance imaging ("MRI"), electroencephalographic activity ("EEG") and behavioral paradigms to demonstrate early proof of mechanism and biology in clinical studies in healthy volunteers and patients. In addition, we utilize robust pharmacokinetic and pharmacometrics exposure-response

relationship modeling in our translational and Phase 2 clinical trials to assess the target blood exposure and define the doses of the drug to be evaluated in our clinical trials, which we believe will result in an increased probability of success in the clinic.

As our programs are either already or about to enter registrational phases (Phase 3 trials) we have developed significant expertise in regulatory interactions, manufacturing scale-up and most importantly designing and conducting large scale clinical trials based on patient centricity and diversity practices, rigorous clinical operations procedures focusing on standardization of protocols, robust investigator training, meticulous patient selection, continuous patient safety and data quality monitoring and state-of-the-art statistical and reporting capabilities. This expertise together with our proven track record in execution of mid-stage (Phase 2 trials) is expected to increase the probabilities of technical success of our future trials, limit the placebo effect, ensure safety of our trial participants, and enable the on-time and on-budget delivery of clinical trial results.

Our Lead Product Candidate

BNC210 for the Treatment of Social Anxiety Disorder and Post-Traumatic Stress Disorder

We are developing our lead product candidate, BNC210, a novel, first- and best-in-class orally administered small molecule, for the acute treatment of SAD and chronic treatment of PTSD. BNC210 is a NAM of the α7 receptor and does not exert its effect on the α7 receptor unless in the presence of an agonist, such as ACh. When BNC210 binds to the α7 receptor in the presence of ACh, it normalizes the effect of enhanced ACh signaling, thereby decreasing the flow of Ca^{2+}through the channel and the subsequent downstream neurotransmitter modulation, as seen in Figure 4. We believe that inhibition by BNC210 of α7 receptor dependent neurotransmission in the amygdala, and other areas involved in emotional, cognitive and mood control such as the basal forebrain, the hippocampus and prefrontal cortex is key to its anti-anxiety and anti-depressive potential. BNC210 has demonstrated positive preclinical results in depression- and anxiety-related models, and reduced amygdala activity in GAD patients as well as a statistically significant reduction in panic symptoms in a clinical trial of healthy volunteers who had received cholecystokinin-4 ("CCK-4"), a peptide that induces anxiety and panic symptoms. BNC210's psychoactive profile, its favorable safety and tolerability and pharmacokinetic properties make it an ideal candidate for both acute and chronic treatment across a number of neuropsychiatric diseases including SAD and PTSD.

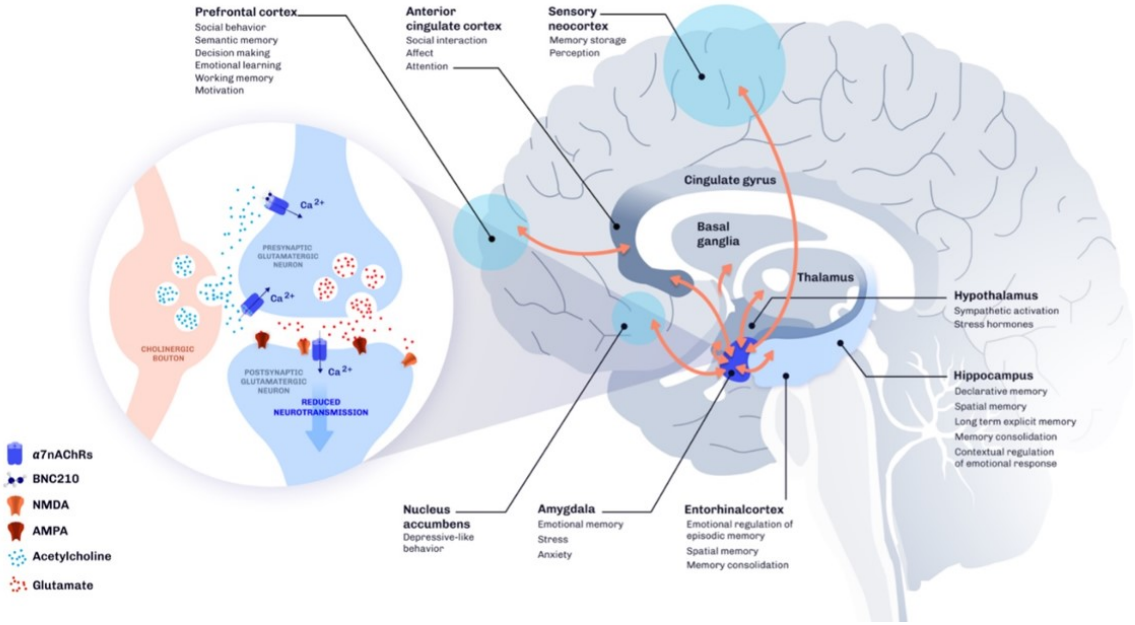

Figure 4. Action of BNC210

While PREVAIL missed its primary endpoint, as measured by the change from baseline to the average of the SUDS scores during a 5-minute Public Speaking Challenge in the BNC210-treated patients when compared to placebo, the December 2022 topline data readout revealed encouraging trends in the prespecified endpoints that focused on individual phases of the public speaking task. The

findings did indicate a consistent trend toward improvements across primary and secondary endpoints and a favorable safety and tolerability profile consistent with previously reported results. We recently completed an FDA End-of-Phase 2 meeting to discuss the registrational program for BNC210 in SAD. On October 11, the Company received the official meeting minutes from the End-of-Phase 2 meeting with the FDA held on September 13, 2023 reflecting that the Company has reached an agreement with the FDA on 1) the plan to conduct two single dose randomized, placebo-controlled studies; 2) the use of the SUDS measured during a public speaking challenge as the primary efficacy endpoint; 3) the doses of BNC210 to be studied in Phase 3; 4) the sample size assumptions for the Phase 3 controlled studies based on PREVAIL findings; 5) the design elements of the open label safety study; 6) the size of the safety database to support the NDA; and 7) the nonclinical toxicology studies needed to support the NDA. In July 2024, we announced the initiation of patient screening for the Phase 3 AFFIRM-1 trial evaluating the safety and efficacy of BNC210 for the acute, as-needed treatment of SAD. AFFIRM-1 targets enrollment of approximately 332 adult patients with SAD at clinical sites in the United States. It is a multi-center, double-blind, two-arm, parallel group, placebo-controlled trial. Participants will be randomized 1:1 to receive a single dose of 225 mg BNC210 or matched placebo about one hour before speaking in public. The primary endpoint will compare BNC210 to placebo using the SUDS to measure self-reported anxiety levels during a public speaking task. Secondary efficacy endpoints include the CGI and PGI scales and the STAI. Topline results from the AFFIRM-1 trial are expected early in the fourth quarter of calendar 2025.

In September 2023, we announced the results of the Phase 2b ATTUNE study which was a double-blind, placebo-controlled trial conducted in a total of 34 sites in the United States and the United Kingdom, with 212 enrolled patients, randomized 1:1 to receive either twice daily 900 mg BNC210 as a monotherapy (n=106) or placebo (n=106) for 12 weeks. The trial met its primary endpoint of change in CAPS-5 total symptom severity score from baseline to Week 12 (p=0.048). A statistically significant change in CAPS-5 score was also observed at Week 4 (p=0.016) and at Week 8 (p=0.015). Treatment with BNC210 also showed statistically significant improvement both in clinician-administered and patient self-reporting in two of the secondary endpoints of the trial. Specifically, BNC210 led to significant improvements at Week 12 in depressive symptoms (p=0.041) and sleep (p=0.039) as measured by MADRS and ISI, respectively. BNC210 also showed signals and trends across visits in the other secondary endpoints including the CGI-S, PGI-S and the SDS. In July 2024, we announced a positive outcome of an End-of-Phase 2 meeting with FDA. The Company presented the clinical plans to registration, that alongside the positive Phase 2b ATTUNE trial include a single placebo-controlled registrational trial with a 52-week open-label extension. The meeting, held on June 26, 2024, was centered around the design of this trial that if successful may enable review of the NDA submission. Key outcomes from the discussion on the trial design included the following:

- Agreement was reached on the use of CAPS-5 as the primary endpoint measure and the CGI-S scale as a key secondary endpoint measure in the placebo-controlled part of the study;
- Agreement was reached that in addition to the efficacious dose of 900 mg twice daily, a lower dose of BNC210 that strikes the right balance between maintenance of efficacy and safety related to LFT findings will be tested;
- High-level agreement was reached on study participant characteristics and sample size assumption methodology; and
- The Company received guidance related to the proposed hepatic safety monitoring plan, including monitoring for excessive alcohol use that will be implemented in the planned Phase 2b/3 trial.

The company is finalizing the full study protocol and contingent upon having sufficient capital on hand, anticipates beginning the Phase 2b/3 program in PTSD in the first half of 2026.

Disease Background and Key Disease Drivers

Social Anxiety Disorder

Social Anxiety Disorder is a serious anxiety condition characterized by the persistent, intense fear of social or performance-related situations in which an individual is exposed to unfamiliar people or to possible scrutiny by others. SAD can also manifest from specific triggers such as a fear of public speaking or be induced by social interactions across any variety of situations. Those suffering from SAD often fear that they will act in a way or show anxiety symptoms that will be embarrassing and humiliating, thus further inducing anxiety. This fear can affect work, school, and other day-to-day activities and can even make it hard to develop and maintain friendships. Most cases of SAD develop in adolescence or early adulthood and without treatment it can last for many years or a lifetime and can prevent individuals from reaching their full potential.

According to the U.S. National Institute of Mental Health, the 12-month prevalence of SAD among adults aged 18 years or older in the United States is 7.1% and it is estimated that 12.1% will experience SAD in their lifetime. Currently, SAD affects approximately 15 million adults in the United States, making it the second most-commonly diagnosed anxiety disorder after phobias. The prevalence is slightly higher for females at 8.0% than males at 6.1%. SAD typically begins around age 13 and it is estimated that 9.1% of adolescents will experience SAD, similarly with higher prevalence rates for females at 11.2% than males at 7.0%. According to the Anxiety and Depression Association of America, 36% of people with SAD report experiencing symptoms for ten or more years before

seeking help. Based on the early age of onset of SAD and the shortcomings of currently approved therapeutics, we believe SAD is underdiagnosed and the size of the potential patient population could be considerably underestimated.

Post-Traumatic Stress Disorder

Post-Traumatic Stress Disorder is a serious, chronic mental health condition triggered by a trauma such as experiencing or witnessing actual or threatened death, serious injury or sexual violence. While historically misunderstood as stemming primarily from traumatic experiences of military personnel in combat, PTSD can also stem from a broad range of other experiences such as a natural disaster, a car accident, repeated exposure to traumatic events as a first responder, childhood trauma and sexual assault. Trauma exposure can trigger a distinctive pattern of persistent, disabling behavioral and physiological symptoms, which include intrusive memories and nightmares of the trauma, severe anxiety, irritability, hypervigilance, depression, difficulty sleeping, poor concentration and emotional withdrawal.

PTSD significantly impacts all aspects of life and the day-to-day functioning of people with this debilitating disorder. In addition, PTSD severity is often worsened by co-occurring disorders that result from PTSD itself such as major depression, substance abuse, and mood and anxiety disorders. PTSD also substantially contributes to suicide risk, further underscoring the severity and unmet need in this patient population. The CAPS is considered to be the gold-standard criterion measure to diagnose and assess the severity of PTSD symptoms in patients in clinical trials. CAPS is routinely updated to reflect the current DSM criteria, the latest of which is the CAPS-5. This scale measures the frequency and intensity of PTSD symptoms, which can be broadly classified into four clusters: intrusion, avoidance, negative mood and thinking, and arousal and reactivity.

Approximately 9 million people currently suffer from PTSD in the United States, a figure which is on the rise due to the impact of the COVID-19 pandemic that has contributed to higher rates of symptoms associated with anxiety, depression and PTSD. Approximately 8% of the U.S. population will experience PTSD within their lifetimes, making PTSD the fifth most prevalent mental health disorder in the United States. In addition, when adjusted for the frequency of traumatic event exposure, women are four times more likely to develop PTSD than men. PTSD is a complex, chronic disorder, with many symptoms and co-morbidities that make it difficult to treat.

Current Treatments for SAD and PTSD and Their Limitations

There remains a significant unmet medical need for over 27 million patients suffering from SAD and PTSD. Current approved pharmacological treatments include SSRIs and SNRIs, with some off-label use of benzodiazepines and beta blockers (only used for SAD). These existing treatments have multiple shortcomings, such as a slow onset of action of antidepressants, and significant side effects of these classes of drugs.

- *Antidepressants.* Antidepressants, including SSRIs and SNRIs, currently serve as first-line pharmacotherapies for SAD and PTSD and SAD. The efficacy shortcomings of these antidepressants are well-known and many patients do not achieve clinical remission, resulting in high discontinuation of therapy. For example, current estimates indicate that only 20 to 30% of PTSD patients achieve clinical remission on SSRI therapies. SSRIs/SNRIs also have tolerability issues, including gastrointestinal side effects, CNS side effects (agitation, anxiety, insomnia, dizziness and drowsiness), sexual dysfunction and sweating and also carry a black-box label warning for increased risk of suicidality in adolescents. Apart from limited or no efficacy, many patients discontinue treatment as a result of the fear of related side effects. Furthermore, SSRIs/SNRIs typically require several weeks of chronic administration before onset of efficacy, making them inadequate for the treatment of acute anxiety episodes in anxiety disorders such as SAD and as often seen in PTSD. Patients on these antidepressants often need co-administration of acute anti-anxiety medications, such as benzodiazepines.

- *Benzodiazepines*. While not FDA approved for SAD or PTSD, benzodiazepines may be prescribed off-label along with approved medications such as SSRIs/SNRIs. In addition to their distinctive sedative effects, benzodiazepines have other significant safety risks, including memory and motor impairment, serious risk of abuse, addiction, physical dependence, and withdrawal reactions, as highlighted in the FDA's Drug Safety Communication in September 2020. Furthermore, emerging evidence indicates that benzodiazepines may inhibit brain areas involved in fear learning, including the amygdala, further delaying recovery and counteracting the effects of the treatment.

- *Beta Blockers*. Beta blockers are a class of blood pressure lowering medications that are commonly used off-label for patients with SAD to help reduce some of the physical symptoms of anxiety, such as an increased heart rate, sweating, or tremors. However, these therapies have not been effective in reducing overall anxiety.

Due to the shortcomings of existing therapies, there remains a significant unmet medical need for improved therapeutics for SAD and PTSD and SAD with improved efficacy and response rates, fewer side effects and a faster onset of action, which we believe may be met by targeting a different mechanism of action.

Potential Advantages of BNC210 for the Treatment of Anxiety and Stressor-Related Disorders

In early acute clinical trials, BNC210 has demonstrated a fast onset of action and the potential for anti-anxiety benefits without many of the limiting side effects observed with benzodiazepines, SSRIs and SNRIs. Based on extensive data from preclinical studies and clinical trials, we believe BNC210 could have a number of potential advantages over drugs currently used to treat anxiety, depression and PTSD, including:

- •fast acting with the potential to be used in acute and chronic settings;
- •non-sedating;
- •no addictive effect and lack of discontinuation/withdrawal syndrome;
- •no memory impairment;
- •no impairment of motor coordination; and
- •no suicidality.

CURRENT THERAPIES FOR THE TREATMENT OF ANXIETY AND STRESSOR-RELATED DISORDERS*

DRUG	FAST ACTING	NO SEDATION	NO WITHDRAWAL SYNDROME	NO MEMORY IMPAIRMENT	NO MOTOR IMPAIRMENT
Benzodiazepines[1]	✓	X	X	X	X
SSRIs / SNRIS[2]	X	✓	X	✓	✓

1. Includes Valium and certain other benzodiazepines.
2. Includes Prozac and certain other SSRIs / SNRIs.

* We have not conducted head-to-head studies to assess the potential benefits of BNC210 compared to benzodiazepines or SSRIs/SNRIs and data from separate studies may not be directly comparable due to differences in study protocols, conditions and patient populations. Accordingly, cross-trial comparisons may not be reliable predictors of the relative activity or other benefits of BNC210 compared to existing therapies or other product candidates that may be approved or are in development for the treatment of PTSD or SAD. The potential benefits of BNC210 does not imply an expectation of regulatory approval which is solely within the authority of the FDA (or applicable foreign regulator).

Figure 5: Current therapies for the treatment of anxiety and stressor-related disorders

Clinical Development of BNC210

To date, we have studied BNC210 in approximately 790 subjects across 15 clinical trials, including in healthy volunteers, elderly patients suffering from agitation and patients with GAD, SAD and PTSD. BNC210 has not demonstrated the severe side effects commonly associated with SSRIs/SNRIs and benzodiazepines. We believe that the tolerability data that we have observed to date supports both acute and chronic dosing.

The table below summarizes our completed clinical trials for BNC210:

Summary of BNC210 Completed Clinical Trials

Phase	Description	Participants / Setting	Subjects Enrolled / Administered BNC210*	BNC210 Formulation and Doses	Location
1	Single Ascending Dose Safety and PK	Healthy volunteers / In-clinic	32/24	Suspension; 5 to 2000 mg (single dose)	Australia
1	Single Ascending Dose Safety and PK; Food Effect	Healthy volunteers / In-clinic	4/3	Suspension; 300 to 2000 mg (single dose)	Australia
1	Single Ascending Dose Safety and PK; Food Effect	Healthy volunteers / In-clinic	47/40	Capsule; 300 to 3000 mg (single dose)	US
1b	Lorazepam Comparison	Healthy volunteers / In-clinic	24/22	Suspension; 300 and 2000 mg (single dose)	France
1b	CCK-4 Panic Attack Model	Healthy volunteers / In-clinic	60/59	Suspension; 2000 mg (single dose)	France
1b	Multiple Ascending Dose Safety and PK; Expanded Cohort for EEG Target Engagement	Healthy volunteers / In-clinic	56/44	Suspension; 150 to 1000 mg twice daily for 8 days	France
1	Suspension and Tablet Formulation PK Comparison	Healthy volunteers / In-clinic	6/6	Suspension and tablet; 300 mg (single dose)	Australia
1	Single Ascending Dose Safety and PK	Healthy volunteers / In-clinic	5/5	Tablet; 600 to 1200 mg (single dose)	Australia
1	Multiple Dosing Safety and PK	Healthy volunteers / In-clinic	10/10	Tablet; 900 mg twice daily for 7 days	Australia
2a	Imaging and Behavioral Study in Generalized Anxiety Disorder	Generalized anxiety disorder patients / In-clinic	27/25	Suspension; 300 and 2000 mg (single dose)	UK
2a	Agitation in the Elderly in Hospital Setting	Agitated elderly patients / Hospital	38/18	Suspension; 300 mg twice daily for 5 days	Australia
2	RESTORE PTSD	PTSD patients / Out-patient	193/143	Suspension; 150, 300 or 600 mg twice daily for 12 weeks	Australia US
2b	ATTUNE PTSD	PTSD patients / Out-patient	212/106	Tablet; 900 mg twice daily for 12 weeks	US, UK
2	PREVAIL SAD	SAD patients / In-Clinic	151/101	Tablet; 225 or 675 mg (single dose)	US

CCK-4 = cholecystokinin tetrapeptide; EEG = electroencephalography; PK = pharmacokinetic.

* The number of enrolled subjects who were administered BNC210; other enrolled subjects were administered placebo or lorazepam only.

Across all 14 completed clinical trials, including two 12-week Phase 2 PTSD trials, the most commonly reported adverse events for participants receiving BNC210 were headache (16%), somnolence (7%) and nausea (6%). The majority of these adverse events were graded as mild and there were no dose-related trends. There have been two serious adverse events ("SAEs") that were deemed by the investigators to be at least possibly related to BNC210: one SAE reported for hypotension (with alternative causality of dehydration) for an elderly patient was deemed possibly related to study drug by the independent investigator, however, after a saline infusion, blood pressure returned to within normal limits within 45 minutes and the subject continued on the study; and one SAE for elevated LFTs reported 14 days after last treatment dose for a PTSD subject who remained asymptomatic throughout the study and in follow up was deemed probably related to study drug by the independent investigator. For the SAE related to elevated liver function, it was subsequently noted in a safety report to the FDA that the Independent Safety Monitoring Board for the study did not consider that this adverse event met the criterion for an SAE. Subsequently the event was deemed as unlikely related to BNC210 by an independent expert hepatologist with recognized expertise in evaluating drug-induced liver injury. However, there were 14 reports of elevated LFT results in participants receiving BNC210 900 mg twice daily in the ATTUNE PTSD study. There have been no apparent BNC210 dose-related trends in vital signs, physical examinations, or electrocardiogram ("ECG") measurements across the 14 completed clinical trials. In addition, we evaluated the abuse potential of BNC210 in three healthy volunteer studies at doses up to 2000 mg per day for eight days using the Addiction Research Center Inventory 49 item questionnaire ("ARCI49"), which showed no significant effects in addiction potential across the five abuse-potential categories evaluated.

Phase 1 Clinical Trial Demonstrating Lack of Benzodiazepine-like Side Effects in Healthy Subjects

We conducted a Phase 1 double-blind, placebo-controlled, four-way crossover clinical trial in 24 healthy subjects to evaluate safety and tolerability of BNC210. These subjects were administered four different treatments in a randomized sequence with a wash-out period of at least seven days between each treatment. The four different treatments consisted of a single dose of placebo, 2 mg lorazepam, 300 mg BNC210 and 2000 mg BNC210. The primary endpoint of the trial was change in attention and the secondary endpoints were changes in visual-motor coordination, emotion, sedation, cognition, ARCI49 and EEG activity. BNC210 had no observed effect on measures of attention, visual-motor coordination, addiction, emotion, sedation or cognition. In contrast, lorazepam demonstrated impairment of all parameters.

Phase 1 Clinical Trial Demonstrating Target Engagement in Brain at Nicotinic Receptor in Healthy Subjects

We conducted a Phase 1 clinical trial to demonstrate BNC210 target engagement at brain nicotinic receptors measured by EEG activity (see Figure 6). On Day -1, one day prior to administration of BNC210, 24 healthy volunteers were administered oral doses of nicotine ranging from 0.5 to 2.0 mg. We then measured the change in the power in the α2 EEG band, a measure of nicotine response in the brain. We observed a dose-dependent increase in power in the α2 EEG band following nicotine administration, which we believe is primarily attributable to the activation of two key nicotinic receptors: α4ß2 and α7. Subjects were then dosed orally with the 2000 mg BNC210 liquid suspension with food for seven days and were re-challenged on Day 7 with the same doses of nicotine used on Day -1. BNC210 demonstrated a statistically significant reduction in the power in the α2 EEG band following nicotine administration, which we believe demonstrates target engagement and negative modulation of the α7 receptor. We believe the residual nicotine-induced EEG responses of subjects treated with BNC210 is primarily attributable to the activation of the α4ß2 nicotinic receptor, which BNC210 is not designed to engage.

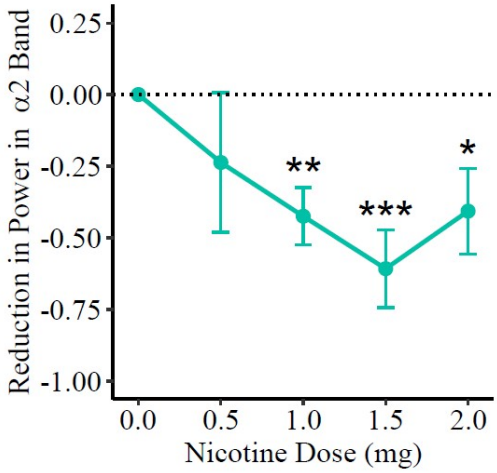

*Figure 6: BNC210 reduced nicotine-induced quantitative wake EEG responses in the power of the a2 band after 7 days of dosing compared to pre-dose suggesting target engagement of the a7 receptor. * p<0.05, ** p<0.01, *** p<0.001.*

Phase 1 and 2 Clinical Trials Demonstrating Anti-Anxiety Effects in Healthy Subjects and Anxiety Patients

We conducted a randomized, placebo-controlled, double-blind Phase 1 clinical trial in 60 healthy subjects to evaluate the anti-anxiety effects of BNC210. These subjects were administered CCK-4, a peptide that induces anxiety and panic symptoms. CCK-4 induced panic symptoms in 15 subjects, or approximately 25% of the subjects, which is consistent with the CCK-4 induced panic attack rate in other trials. Subjects in a supervised in-clinic setting received a single dose of 2000 mg of BNC210 liquid suspension formulation with food seven hours prior to the CCK-4 challenge. BNC210 demonstrated statistically significant reduction in both the intensity and number of panic symptoms on the Panic Symptoms Scale (“PSS”) compared to placebo 10 minutes after the CCK-4 injection, as seen in Figure 7 (p=0.041 and p=0.048, respectively). This clinical trial also demonstrated that there was a trend for BNC210-treated subjects to return to baseline emotional stability more quickly than for placebo-treated subjects. These findings were consistent with

our prior preclinical studies in rodents where BNC210 overcame the effects of a CCK-4 challenge and enhanced fear extinction, as well as demonstrated similar activity to benzodiazepines without the narrow dose response common to that class of drugs.

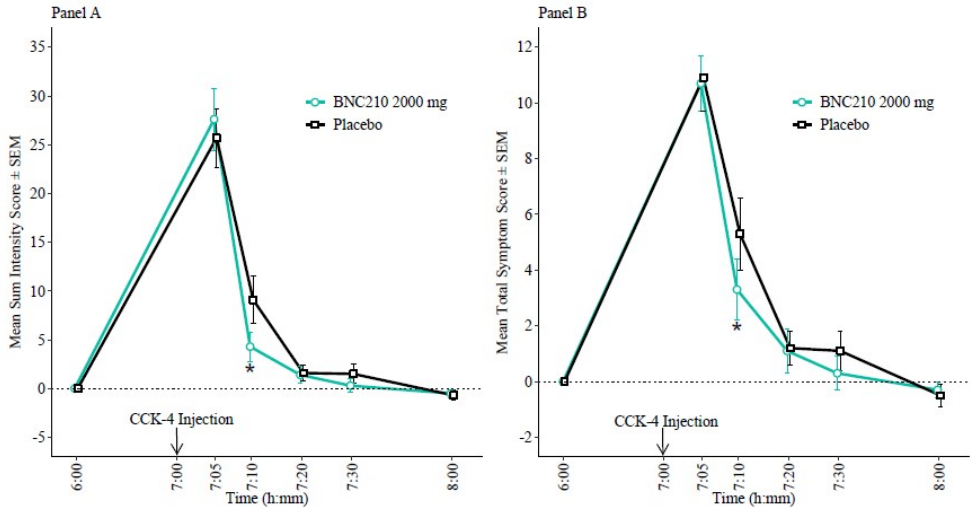

*Figure 7: Mean change from baseline for (A) Sum Intensity score (panic symptom intensity) and (B) Total Symptom score (total number of panic symptoms) on the Panic Symptom Scale. *p<0.05 vs. placebo.*

We also conducted a Phase 2 randomized, double-blind, placebo-controlled, four-way crossover clinical trial in 24 newly diagnosed, treatment-naive GAD patients in the in-clinic setting evaluating the neural imaging response of patients exposed to "fearful faces" and their behavioral response to threat avoidance. Each subject was treated in a randomized manner with a single dose of 300 mg BNC210, 2000 mg BNC210, 1.5 mg lorazepam or placebo with a washout period of at least five days. The primary endpoints were changes in cerebral perfusion using functional MRI in the resting state and changes in activation of the region of the brain responsible for emotional control, the amygdala, during the performance of an emotional task. Secondary endpoints were changes in defensive behavior (Flight Intensity) using the Joystick Operated Runway Task ("JORT") and changes in affective self-report, which are measures of anxiety. BNC210 300 mg, similarly to lorazepam, statistically significantly reduced amygdala reactivity to "fearful faces" relative to placebo (BNC210 300 mg left amygdala p=0.011; BNC210 300 mg right amygdala p=0.006; lorazepam right amygdala p=0.047) (Figure 8A). BNC210 300 mg also statistically significantly reduced connectivity between the amygdala and the anterior cingulate cortex ("ACC"), a network involved in regulating anxious responses to aversive stimuli (p=0.012) (Figure 8B). Furthermore, in this head-to-head study, BNC210 300 mg and 2000 mg statistically significantly reduced the intensity of defensive behavior compared to placebo, while lorazepam did not (BNC210 300 mg p=0.007; BNC210 2000 mg p=0.033) (Figure 8C). In addition, the 300 mg dose of BNC210 significantly reduced self-reported anxiety (p=0.003).

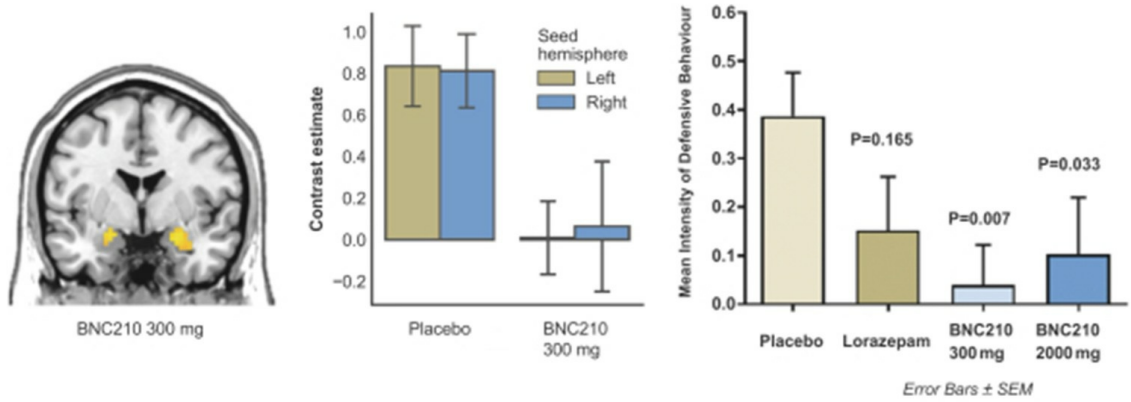

Figure 8: Phase 2 trial in GAD patients. (A) BNC210 300 mg significantly reduced activation of the left and right amygdala while viewing fearful faces; (B) BNC210 300 mg significantly reduced connectivity between the amygdala and ACC while viewing fearful faces; (C) BNC210 300 mg and 2000 mg significantly reduced threat avoidance behavior in the JORT behavioral task.

Novel, Proprietary Tablet Reformulation Effort

The earlier clinical trials discussed above were carried out with a liquid suspension formulation of BNC210. The liquid suspension formulation was required to be given (in-clinic) or taken (outpatient) with a high fat food diet to provide optimal absorption of the drug candidate. While the liquid suspension formulation of BNC210 performed well in the in-clinic supervised setting, we believe it was inadequate for outpatient studies due to substantially lower blood exposure, higher variability and/or lower compliance. To overcome the limitations of the liquid suspension formulation in providing adequate exposure in the outpatient setting, we developed a novel, proprietary tablet formulation to use in subsequent studies with the goals of overcoming the food effect (i.e. the requirement to be given with food), improving patient compliance and providing rapid absorption and dose linear pharmacokinetics. We conducted three clinical trials to evaluate the pharmacokinetics of the tablet formulation including a comparison with the liquid suspension formulation, a single ascending dose study and a seven-day multi-dosing study. The tablet formulation was used in the Phase 2b PTSD ATTUNE trial, and Phase 2 SAD PREVAIL trial, and is being used in the ongoing Phase 3 AFFIRM-1 trial.

We conducted a Phase 1 clinical trial to compare a single BNC210 300 mg dose of the liquid suspension formulation to the tablet formulation in six fasted and fed healthy subjects in a cross-over design in which each subject received three treatments with a wash-out period of at least five days in between: (i) fasted subjects who received the liquid suspension formulation; (ii) fasted subjects who received the tablet formulation and (iii) fed subjects who received the tablet formulation. As can be seen in the figure below, fasted subjects that were administered liquid suspension formulation resulted in substantially lower BNC210 blood levels and exposure in comparison to fed subjects from a prior study. By contrast, administration of the new tablet formulation in fasted or fed subjects resulted in similar blood concentrations and exposure (i.e., area under the curve (“AUC”) with a delay in time to maximal concentration (“tmax”) in fed individuals as would be expected with delayed absorption of the drug. More importantly, the exposure in fasted or fed subjects administered the tablet formulation of BNC210 was comparable to the exposure seen in subjects given the liquid suspension formulation with food (based on data from the 300 mg suspension dose in the earlier pharmacokinetic study described above). Based on the results of this trial the new tablet formulation simplified dosing in the Phase 2b ATTUNE PTSD clinical trial where subjects were given the option to dose the medication with or without food.

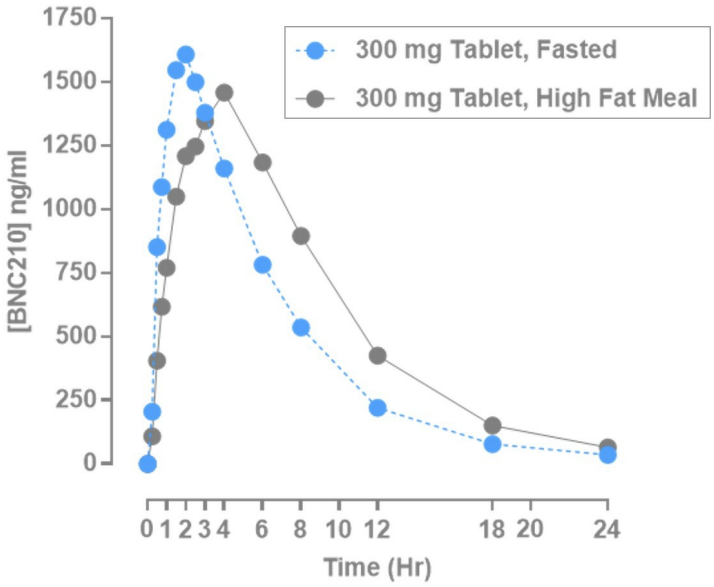

Figure 9: BNC210 tablet formulation overcomes food effect in healthy subjects.

We carried out a second Phase 1 single ascending dose pharmacokinetic clinical trial in five healthy subjects in which each subject, in a fasted state, was dosed with 600 mg, 900 mg, and 1200 mg of BNC210 tablet formulation with a wash-out period of at least five days between treatments. For comparison, the results of the 300 mg dose in fasted subjects from a previous study using the tablet formulation is included in the dataset. The plasma concentrations and exposures measured in fasted healthy volunteers increased in a dose proportional manner, demonstrating improved dose linearity with the tablet formulation compared to the liquid suspension. The BNC210 tablet formulation had a rapid absorption profile reaching maximal concentrations in the blood between 45 to 105 minutes, making it a well-suited formulation for treatment of acute anxiety in SAD patients. BNC210 was observed in this study to be well tolerated at all dose levels tested.

We also carried out a multi-dose seven-day dosing pharmacokinetic study in ten healthy volunteers (five females and five males) to evaluate the dosing regimen (900 mg given twice daily) for the Phase 2b ATTUNE PTSD clinical trial. The results showed that with twice daily dosing there was no gender-based difference in exposure and that BNC210 continued to be well-tolerated, even at the higher exposure levels achieved after seven days of dosing in the healthy volunteers.

BNC210 Clinical Development in SAD

We conducted an SAD trial, which we refer to as the PREVAIL Study, evaluating the effects of acute dosing of BNC210 on anxiety in SAD, using a standardized Public Speaking Challenge. We are building on the favorable attributes of our novel tablet formulation with a rapid absorption profile reaching maximal concentrations in the blood between 45 to 105 minutes, providing the potential for on demand use to treat symptoms of social anxiety which result from often predictable anxiety-provoking stressors.

The PREVAIL Study was a randomized, double-blind, parallel three-arm (placebo, 225 mg BNC210 or 675 mg BNC210), multi-center Phase 2 clinical trial which compared the tablet formulation of BNC210 to placebo on anxiety levels in patients with SAD during an anxiety-provoking behavioral task, i.e., the public speaking challenge (Figure 10). Participants were orally administered a single dose of study treatment approximately one hour prior to the behavioral task. The primary endpoint of the PREVAIL Study was to compare BNC210 to placebo on self-reported anxiety levels using the SUDS during the behavioral task. Secondary endpoints included other scales measuring participants' anxiety levels, in anticipation of, and during the behavioral task, as well as an evaluation of the safety and tolerability of BNC210 in this population. The PREVAIL Study was conducted at 15 sites in the U.S. and enrolled 151 adult patients suffering with SAD. The study participants must have had a score of at least 70 on the Liebowitz Social Anxiety Scale ("LSAS") (i.e., marked to severe social anxiety), which is a scale that assesses a patient's reported level of social phobia in a range of social interactions and performance situations during the past week.

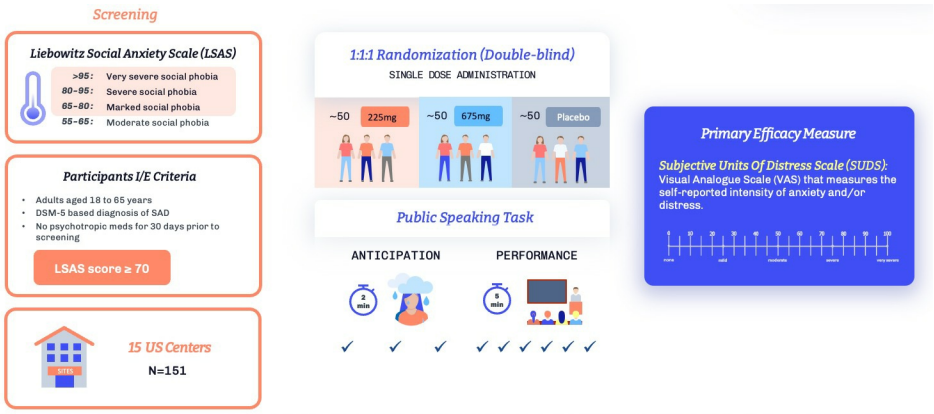

Figure 10: Phase 2 PREVAIL clinical trial design.

The PREVAIL Study was designed with the aim of uncovering the best methodological approaches to measure the therapeutic potential of BNC210 in the acute treatment of SAD, a setting with no approved treatments, and evolving understanding of clinical trial methodologies. While PREVAIL missed its primary endpoint, as measured by the change from baseline to the average of the SUDS scores during a 5-minute Public Speaking Challenge in the BNC210-treated patients when compared to placebo, the December 2022 topline data readout revealed encouraging trends in the prespecified endpoints that focused on individual phases of the public speaking task (although these results are not predictive of future success or similar results). The findings did indicate a consistent trend toward improvements across primary and secondary endpoints and a favorable safety and tolerability profile consistent with previously reported results. These results supported a post-hoc in-depth analysis of the full dataset to better understand the true potential of the drug and guide late-stage trial design. Moreover, administration of both 225 mg and 675 mg BNC210 doses resulted in therapeutic responses of similar magnitude (Figure 11), which allowed for the data from the two arms to be combined in the post-hoc analysis, enhancing the dataset's statistical power (BNC210 n = 101, placebo n = 50).

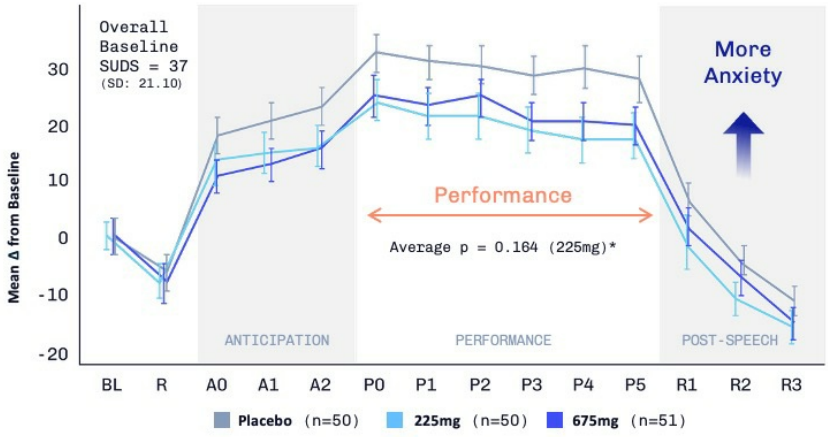

Figure 11: PREVAIL Study – Mean change from baseline in SUDS scores during a Public Speaking Challenge in patients with SAD.

The post-hoc analysis revealed that participants that received BNC210 experienced significantly less anxiety during the public speaking task (combined anticipation and performance phases) compared to participants that received placebo as measured by SUDS (p=0.044) (Figure 12). The therapeutic effects are comparable to those reported with benzodiazepines supporting the clinical meaningfulness of BNC210's anxiolytic effects. Converging trends favoring BNC210 were also observed in the STAI.

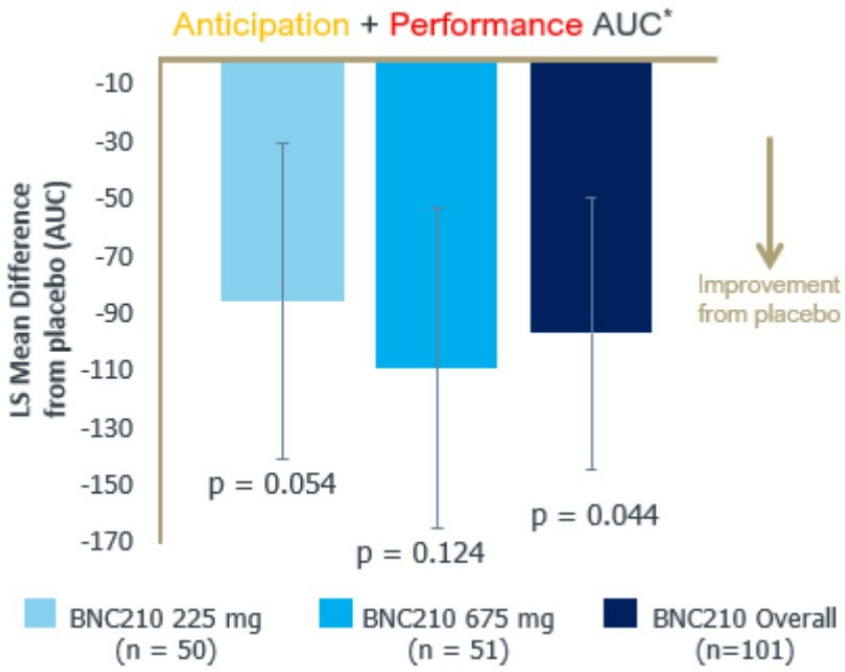

*Figure 12: PREVAIL Study – The combined BNC210 dose group significantly reduced the area-under-the-curve (*AUC) SUDS scores across the anticipation and performance phases of a public speaking challenge compared to placebo.*

In addition to the favorable efficacy, the overall safety profile for 250 mg of BNC210 was found to be consistent with a non-sedating anxiolytic. The new oral tablet formulation performed as predicted by earlier studies in healthy volunteers and exhibited a fast-acting pharmacokinetic profile that supports the use of BNC210 in the acute treatment of SAD. In sum, the complete analysis of the data indicates that patients who received BNC210 exhibited a statistically significant separation over those receiving placebo in a well-powered post-hoc analysis.

In October 2023, the Company received the official meeting minutes from the End-of-Phase 2 meeting with the FDA, reflecting that the Company has reached an agreement with the FDA on the following:

- the plan to conduct two single dose randomized, placebo-controlled studies;
- the use of the SUDS measured during a public speaking challenge as the primary efficacy endpoint;
- the doses of BNC210 to be studied in Phase 3;
- the sample size assumptions for the Phase 3 controlled studies based on PREVAIL findings;
- the design elements of the open label safety study;
- the size of the safety database to support the NDA; and
- the nonclinical toxicology studies needed to support the NDA.

In July 2024, we announced the initiation of patient screening for the Phase 3 AFFIRM-1 trial evaluating the safety and efficacy of BNC210 for the acute, as-needed treatment of SAD. The AFFIRM-1 trial was designed based on the same principles of PREVAIL and was refined based on feedback received during the End-of-Phase 2 meeting with the FDA held on September 13, 2023.

AFFIRM-1 aims to enroll approximately 332 adult patients diagnosed with SAD and who rate ≥ 60 on the LSAS. Study participants are randomized 1:1 to receive a single acute dose of either 225 mg BNC210 or a matched placebo. Approximately 1 hour after dosing, participants are introduced to the public speaking challenge and have 2 minutes to prepare for the speech (anticipation phase). Participants are then required to give a 5-minute speech in front of a small audience (performance phase).

The primary endpoint of the trial is the change from baseline to the average of the performance phase of the public speaking challenge in SUDS scores. Secondary endpoints include change in SUDS score from baseline to the average of the anticipation phase, changes in the CGI-S scale, and self-assessment with the STAI state subscale and the PGI-I scale. A follow-up visit occurs 1 week after the public speaking challenge.

The following diagram describes the Phase 3 AFFIRM-1 clinical trial design:

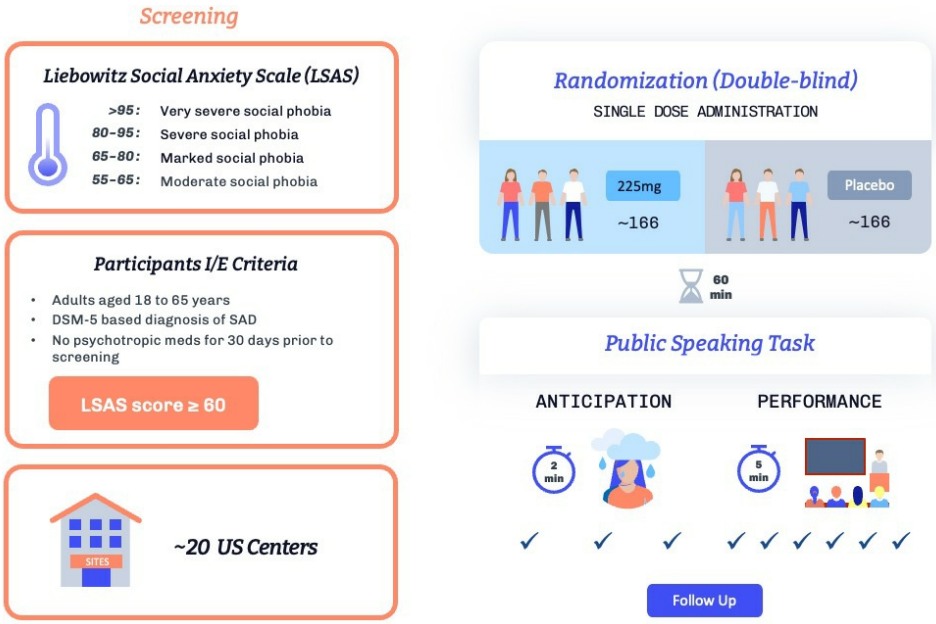

Figure 13: Phase 3 AFFIRM-1 clinical trial design.

Topline results from the AFFIRM-1 trial are expected early in the fourth quarter of calendar 2025.

BNC210 Clinical Development in PTSD

We initiated a Phase 2b clinical trial, which we refer to as the ATTUNE trial, evaluating BNC210 monotherapy treatment in PTSD patients. In April 2023, we completed target enrolment of 212 participants in this clinical trial at 34 sites in the United States and the United Kingdom. ATTUNE was a 1:1 randomized, double-blind, placebo-controlled, parallel two-arm (placebo or BNC210 900 mg twice daily) 12-week treatment study that assessed the efficacy and safety of our newly developed tablet formulation of BNC210. The primary efficacy endpoint of this trial was the effect of BNC210 compared to placebo on baseline to endpoint change in CAPS-5 total symptom severity scores after 12 weeks of treatment. In addition, several investigators and self-reported secondary efficacy endpoints

related to CAPS-5 symptom cluster severity scores and anxiety and depression measures along with safety and tolerability endpoints were reported (Figure 14).

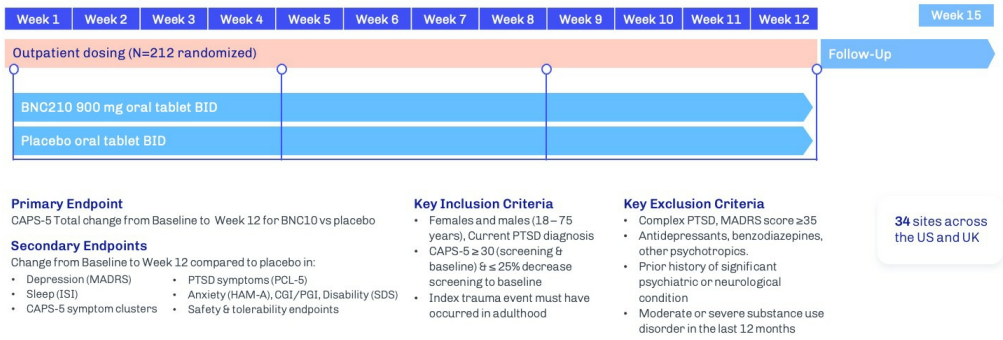

Figure 14: Phase 2b ATTUNE clinical trial design.

In September 2023, we announced the results of the Phase 2b ATTUNE study. The trial met its primary endpoint of change in CAPS-5 total symptom severity score from baseline to Week 12 (p=0.048). A statistically significant change in CAPS-5 score was also observed at Week 4 (p=0.016) and at Week 8 (p=0.015) (Figure 15). Treatment with BNC210 also showed statistically significant improvement both in clinician-administered and patient self-reporting in two of the secondary endpoints of the trial. Specifically, BNC210 led to significant improvements at Week 12 in depressive symptoms (p=0.041) (Figure 16A) and sleep (p=0.039) (Figure 16B) as measured by MADRS and ISI respectively. BNC210 also showed signals and trends across visits in the other secondary endpoints including the CGI-S, PGI-S and SDS. Contingent upon successful capital raise, we are planning to initiate Phase 3 study in PTSD in the second half of 2025.

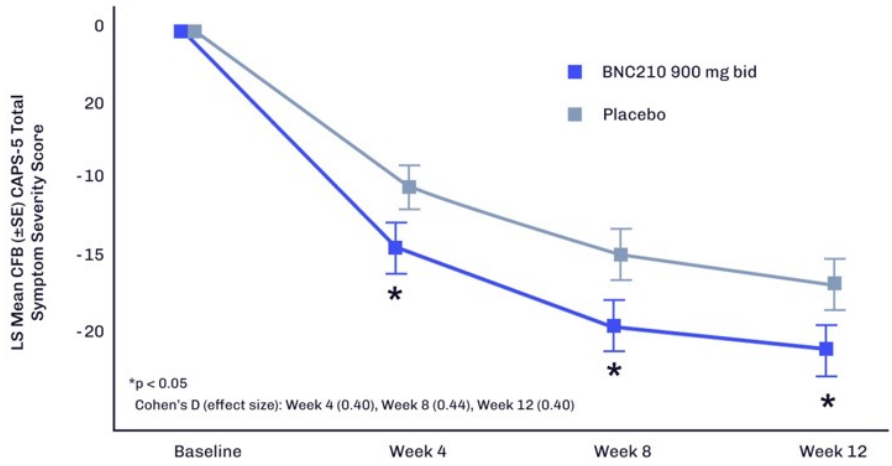

*Figure 15: ATTUNE Study – BNC210 significantly reduced change from baseline CAPS-5 total symptom severity scores in patients with PTSD. *p<0.05.*

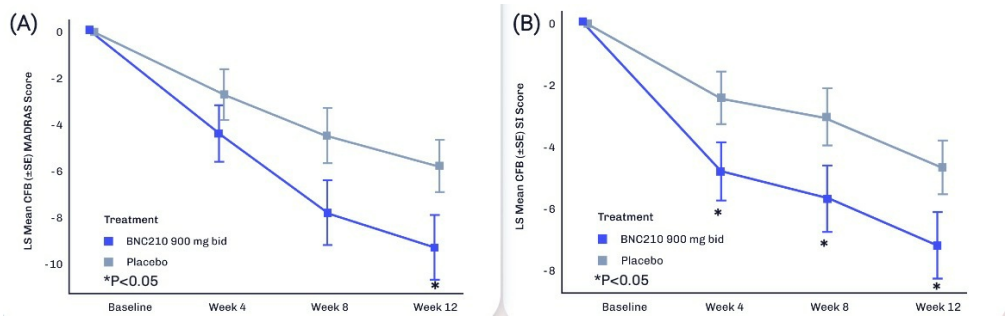

*Figure 16: ATTUNE Study – BNC210 significantly reduced change from baseline (A) MADRS depression scores, and (B) Insomnia Severity Index scores, compared to placebo. *p<0.05*

In July 2024, we announced a positive outcome of an End-of-Phase 2 meeting with the FDA. The Company presented the clinical plans to registration, that alongside the positive Phase 2b ATTUNE trial include a single additional placebo-controlled registrational trial with a 52-week open-label extension. The meeting, held on June 26, 2024, was centered around the design of this trial that if successful may enable review of the NDA submission. Key outcomes from the discussion on the trial design included:

- Agreement was reached on the use of CAPS-5 as the primary endpoint measure and the CGI-S as a key secondary endpoint measure in the placebo-controlled part of the study.
- Agreement was reached that in addition to the efficacious dose of 900 mg twice daily, a lower dose of BNC210 that strikes the right balance between maintenance of efficacy and safety related to LFT findings will be tested.
- High-level agreement was reached on study participant characteristics and sample size assumption methodology.
- The company received guidance related to the proposed hepatic safety monitoring plan, including monitoring for excessive alcohol use that will be implemented in the planned Phase 2b/3 trial.

Contingent upon having sufficient capital on hand, we anticipate beginning the Phase 2b/3 program in PTSD in the first half of 2026.

Future Indication Expansion Opportunities for BNC210

We believe BNC210 has broad potential across acute and chronic anxiety and stressor-related disorders with high unmet medical need. Our clinical, regulatory and commercial strategy is to initially develop BNC210 in an acute indication with a high unmet medical need for which there is no FDA-approved treatment, such as SAD, and a chronic indication with a high unmet medical need, such as PTSD, for which there are limited treatment options. Assessment of BNC210 in these two distinct settings of anxiety and stressor-related disorders will also allow us to define the dosing paradigm which may be applicable to other indications across both acute and chronic settings. BNC210 has already demonstrated the potential for acute treatment of GAD patients in a Phase 2 clinical trial and would represent a logical treatment paradigm for the chronic treatment of this indication along with chronic treatment of SAD and adjustment disorders with anxiety. Additional indications, including panic disorder, are also being considered for both the acute and chronic administration of BNC210.

Other Pipeline Programs

α7 Receptor Positive Allosteric Modulator Program for the Treatment of Cognitive Impairment

Treatments for cognitive deficits associated with CNS disorders such as Alzheimer disease and schizophrenia remain significant unmet medical needs that incur substantial pressure on the healthcare system. The α7 receptor has garnered substantial attention as a target for cognitive deficits based on receptor localization, robust preclinical effects, genetics implicating its involvement in cognitive disorders, and encouraging, albeit mixed, clinical data with α7 receptor orthosteric agonists. Importantly, previous orthosteric agonists at this receptor suffered from off-target activity, receptor desensitization, and an inverted U-shaped dose-effect curve in preclinical assays that limit their clinical utility.

To overcome the challenges with orthosteric agonists, we embarked on an α7 PAM discovery program which led to the identification of BNC375, a novel α7 PAM which is selective over related receptors and potentiates ACh-evoked α7 currents with no observed effect on receptor desensitization kinetics. In June 2014, we entered into a strategic collaboration with Merck to develop novel PAMs, including our BNC375 research program, for the treatment of cognitive dysfunction associated with Alzheimer's disease and other central nervous system conditions. Under the collaboration, BNC375 was further characterized showing that it enhanced long-term

potentiation of electrically evoked synaptic responses in rat hippocampal slices and *in vivo*, which is an established preclinical surrogate for memory enhancement. Systemic administration of BNC375 reversed scopolamine-induced cognitive deficits in rat novel object recognition and rhesus monkey object retrieval detour ("ORD") tasks over a wide range of exposures, showing no evidence of an inverted U-shaped dose-effect curve. The compound also improved performance in the ORD task in aged African green monkeys. African green monkeys display pathological hallmarks of Alzheimer's disease such as amyloid plaques and constitute a valuable translational model to assist in the development of drug candidates for Alzheimer's disease. Moreover, *ex vivo*13C-NMR analysis indicated that BNC375 treatment enhanced neurotransmitter release in rat medial prefrontal cortex. These findings suggest that α7 receptor PAMs may have multiple advantages over orthosteric α7 receptor agonists for the treatment of cognitive dysfunction associated with CNS diseases.

The Merck collaboration currently includes two clinical stage candidates which are PAMs of the α7 receptor (MK4334 and MK-1167) that are being developed for treating cognitive impairment in various CNS disorders. The first compound (MK-4334) has completed Phase 1 safety and biomarker clinical trials in healthy subjects. In 2020, a second molecule (MK-1167) that showed an improved potency profile in preclinical animal models was advanced by Merck into Phase 1 safety and biomarker clinical trials, including, but not limited to, a safety, tolerability and pharmacokinetic study in healthy elderly patients, an efficacy and safety study in patients with Alzheimer's disease taking donepezil treatment (which is used to treat dementia symptoms), and a drug-drug interaction study in healthy volunteers. In December 2024, Merck initiated a Phase 2 clinical trial to evaluate the safety and efficacy of MK-1167, for the treatment of the symptoms of Alzheimer's disease dementia (NCT06721156). This global trial is evaluating the efficacy and safety of MK-1167 as an adjunctive therapy to acetylcholinesterase inhibitor therapy to look for improvements in memory and mental activity. Study treatment (one of three dose levels of MK-1167 or placebo) is administered daily for up to approximately 24 weeks to patients (aged 55 to 90 years) with mild to moderate Alzheimer's disease dementia. The primary endpoint is the change from baseline to Week 24 on the Alzheimer's Disease Assessment Scale-11-item Cognitive Subscale ("ADAS-Cog11"). Target enrollment is 350 participants.

Emerging CNS Programs

We have an emerging CNS pipeline with two small molecule programs targeting ion channels.

Utilizing our expertise in ion channel biology and translational medicine we developed next generation patented orally bioavailable small molecule series of NAM targeting the α7 receptor that can be potentially positioned for the treatment of CNS disorders of high unmet clinical need. A comprehensive overview of α7 NAMs is provided in previous sections.

Kv3.1/Kv3.2 voltage gated potassium channels are pivotal in generating high frequency firing of parvalbumin positive GABAergic interneurons in the prefrontal cerebral cortex involved in regulating cognitive function and social interaction. Pharmacological activation of Kv3.1/Kv3.2 channels may possess therapeutic potential for treatment of schizophrenia, social withdrawal and cognitive impairments. We have patented two series of small molecule Kv3.1/3.2 potassium channel activators for the potential treatment of cognitive deficits and negative symptoms in schizophrenia and for the treatment of autism spectrum disorders including those arising from Fragile X syndrome. Representative molecules from each series have been associated with the reversal of pharmacologically induced cognitive deficits in mouse and rat models at a rate equivalent to risperidone, an antipsychotic drug used to treat schizophrenia, used as the positive control.

Legacy Oncology Programs

We have a portfolio of legacy clinical-stage oncology programs targeting cancer stem cells (BNC101) and tumor vasculature (BNC105) that we have progressed through external funding for clinical trials and out-licensing to capture future value for our shareholders. Cancer stem cells are the seeds that give rise to initial tumor formation and if left unchecked, give rise to tumor recurrence and metastasis. Our first legacy oncology program is BNC101, a novel humanized monoclonal antibody that targets LGR5, a cancer stem cell receptor highly over-expressed in most solid tumors, including colorectal, breast, pancreatic, ovarian, lung, liver and skin cancers. In preclinical studies, BNC101 was associated with a reduction in the frequency of cancer stem cells derived from primary patient colorectal tumors both *in vitro* and *in vivo*. BNC101 has completed a Phase 1 clinical trial in patients with colorectal cancer and shown target engagement. In preclinical studies, BNC101 has shown good potential for the treatment of gastrointestinal tumors in combination with an antibody drug conjugate or CAR-T therapy. In November 2020, we exclusively licensed BNC101 to Carina for the development of CAR-T therapeutics, in return for milestones and royalties or a percentage of the out-licensed revenues. On 24 January 2023, Carina announced that it had received an FDA "Safe to Proceed" Letter for a Phase 1/2a clinical trial of BNC101 CAR-T therapy for the treatment of advanced colorectal cancer. In December 2023, Carina announced that patient dosing for their Phase 1/2a study had commenced.

Our second legacy oncology program, BNC105, is a novel vascular tubulin polymerization inhibitor agent for treatment of cancer, which disrupts the blood vessels that nourish tumors. BNC105 has been evaluated in six prior clinical trials. We plan to advance these oncology programs only through existing and potentially new partnerships.

Competition

The biopharmaceutical industry is highly competitive and subject to rapid and significant technological change. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions.

Key competitive factors affecting the commercial success of our drug candidates, if approved, are likely to be efficacy, safety and tolerability profile, reliability, convenience of dosing, the level of branded and generic competition, price, reimbursement and intellectual property protection.

Our competitors may have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drug candidates, obtaining FDA or European Medicines Authority ("EMA") approvals of comparable products and the commercialization of those products. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a small number of competitors. Accordingly, our competitors may be more successful in obtaining regulatory approval for drugs and achieving widespread market acceptance. Our competitors' products may be more effective, or more effectively marketed and sold, than any drug candidate we may commercialize and may render our therapies obsolete or non-competitive before we can recover development and commercialization expenses.

If competitor companies develop technologies or drug candidates more rapidly than we do, or their technologies are more effective, our ability to develop and successfully commercialize drug candidates may be adversely affected. Our competitors may also obtain FDA, EMA, Therapeutic Goods Administration ("TGA") or other regulatory approval for their products more rapidly than we may obtain approval for ours. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available.

Our competitors fall primarily into the following categories:

- **PTSD**: There are two FDA-approved generic antidepressants indicated to treat PTSD, sertraline (Zoloft) and paroxetine (Paxil). In addition, the most recent and relevant PTSD treatment guidelines from the American Psychological Association and the U.S. Department of Veteran Affairs and Department of Defense published in 2017 also recommend fluoxetine (Prozac) or venlafaxine (Effexor). We are aware of other companies seeking to find improved therapeutics for PTSD by exploring mechanisms of action different from the approved SSRIs, including Lykos Therapeutics, among others.

- **SAD**: There are currently no FDA-approved drugs for the acute treatment of SAD. There are three FDA-approved generic antidepressants for treatment of SAD that include paroxetine (Paxil), sertraline (Zoloft) and venlafaxine (Effexor). Although not FDA-approved for the acute treatment of SAD, generic benzodiazepines and beta blockers are used off-label use as well. Additionally, we are aware of several product candidates in clinical development that are being developed for the acute treatment of SAD, by VistaGen Therapeutics, among others.

Manufacturing

We do not have our own manufacturing facilities or personnel and rely on third parties for the manufacturing, filling, labeling, packaging, storing and distribution of our investigational drug products and product candidates for preclinical and clinical testing, and if we receive regulatory approval, we will continue to rely on such third parties for commercial manufacturing of our product candidates. It is our intent to identify and qualify additional manufacturers to provide active pharmaceutical ingredient and formulate drug product, as well as fill-and-finish services prior to submission of an NDA to the FDA for any product candidates that complete clinical development.

BNC210 is a are small molecule and is manufactured in a reliable and reproducible synthetic process from readily available starting materials. The chemistry does not require highly specialized equipment in the manufacturing process. We expect to continue to develop product candidates that can be produced cost-effectively at contract manufacturing facilities.

Commercialization

Given our stage of development, with respect to BNC210, we have not yet established a commercial organization or distribution capabilities, nor have we entered into any partnership or co-promotion arrangements with an established pharmaceutical company. We intend to develop and, if approved by the FDA, to commercialize our product candidates in the United States. For PTSD or the acute treatment of SAD, we intend to commercialize our product candidates, if approved, independently or enter into co-promotion arrangement in the United States. For other psychiatry indications, we may work in combination with one or more large pharmaceutical partners, where specialist capabilities are needed. With respect to countries outside the United States, we plan on

establishing partnerships following demonstration of proof-of-concept for our product candidates and work with our ex-U.S. partners to develop an integrated global clinical development and registration plan if the opportunity presents itself.

Research Collaboration and License Agreement with Merck

In June 2014, we entered into a License Agreement with Merck to develop α7 receptor PAMs targeting cognitive dysfunction associated with Alzheimer's disease and other CNS conditions. Under the 2014 License Agreement, Merck funded certain research and development activities on a FTE basis pursuant to a research plan. Merck funds current and future research and development activities, including clinical development and worldwide commercialization of any products developed from the collaboration. The Merck collaboration currently includes two clinical stage candidates which are PAMs of the α7 receptor (MK4334 and MK-1167) that are being developed for treating cognitive impairment in various CNS disorders.

We received upfront payments totaling $20 million, which included funding for FTEs for the first twelve months, and another $10 million in February 2017 when the first compound from the collaboration-initiated Phase 1 clinical trials. On March 19, 2025, the Company received a $15 million milestone payment from Merck. The payment was triggered by the initiation by Merck of a Phase 2 clinical trial to evaluate the safety and efficacy of MK-1167, an α7 nicotinic acetylcholine receptor PAM, for the treatment of the symptoms of Alzheimer's disease dementia (NCT06721156). This $15 million payment marks the third milestone achieved in the collaboration with Merck. Under the agreement, as amended, Neuphoria is eligible to receive up to $450 million in additional research and commercial milestone payments for certain development and commercial milestones associated with the progress of multiple candidates, plus royalties on net sales of any licensed medicines.

Merck controls the clinical development and worldwide commercialization of any products developed from the collaboration and therefore we cannot predict whether or when we might achieve any milestone payments under the collaboration or estimate the full amount of such payments, and we may never receive any such payments. Further, we are subject to limited information rights under the 2014 Merck License Agreement. As such, we are dependent on Merck to provide us with any updates related to clinical trial results, serious adverse events and ongoing communications with FDA or other regulatory agencies related to these programs, which Merck may provide or withhold in its sole discretion, and as a result we may not be able to provide material updates on a timely basis or at all with respect to these programs.

The Company evaluated the Merck Agreement in accordance with the provisions of Accounting Standards Codification Topic 606, Revenue from Contracts with Customers ("ASC 606"). The Company's obligation under the Merck Agreement related to the residual variable consideration associated with the Merck Agreement are as follows: the Company granted to Merck an exclusive license (even as to the Company and its Affiliates) in the Territory under the Bionomics Ltd. Patent Rights and Bionomics Ltd. Know-How, with a right to grant and authorize sublicenses, to research, develop, make, have made, use, offer to sell, sell, import and/or otherwise exploit Compounds and Products in the Field.

Regulatory milestone payments are triggered upon the achievement of certain research and commercial milestones. The commercial milestone payments and royalties are subject to the royalty recognition constraint whereby such amounts will be recognized as revenue upon the later of: (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the payment has been allocated has been satisfied, or partially satisfied, because the exclusive license is deemed to be the sole or predominant item to which the payments relate. As all performance obligations are satisfied, the Company will recognize royalty revenue at the date the sales occur.

On March 14, 2025, the Company and Merck executed the Fifth Amendment to the Research Collaboration and License Agreement which amended the patent royalty rate set out in the Agreement, such that, conditioned upon achievement of net sales thresholds set forth in the Merck Agreement, as amended, the Company will be paid royalties on net sales ranging from a low single digits percentage to a low sub-teens percentage, depending on net sales volume. There were no other changes in the transaction price during the fiscal year ended June 30, 2025.

IP License Agreement with Carina Biotech

In November 2020, we entered into an IP license agreement (the "Carina Biotech License") with Carina. Pursuant to the Carina Biotech License, we granted Carina an exclusive, worldwide license, with the right to grant sublicenses (subject to certain restrictions), under certain of our patents and know-how to research, develop, make, have made, use, sell, offer for sale, supply, cause to be supplied, import and otherwise exploit products applying the licensed patents and/or licensed know-how for research, commercial and development applications, and related fields, with respect to CAR-T cells, adaptor CARs and other adoptive cell therapies.

Under the Carina Biotech License, Carina is obligated to use commercially reasonable efforts to commercially develop and exploit licensed products in each country in which Carina obtains regulatory approval for the licensed products. Carina is responsible for

conducting all regulatory activities for the licensed products. We are obligated to assist Carina as reasonably requested from time to time in connection with its regulatory filings. We are also obligated to provide technology transfer to Carina, at Carina's request, of know-how and technical information that is useful or necessary for Carina to fully exercise the rights licensed to it under the agreement.

Pursuant to the Carina Biotech License, we are eligible to receive up to A$118 million in certain development, regulatory and commercial milestone payments if Carina Biotech fully develops and markets the new therapy. Carina Biotech is also obligated to pay us royalties on its net sales of licensed products, on a country-by-country and product-by-product basis, ranging from the low single digits to the mid-single digits, subject to certain specified deductions. Royalties are payable until the later of expiration of all licensed patents covering the licensed products, or expiration of all data exclusivity with respect to the licensed product. If Carina Biotech enters into one or more sublicensing agreements relating to the licensed product, we are eligible to receive a percentage of sublicensing revenues.

The Carina Biotech License expires upon the last to occur of expiration of all licensed patents having a valid claim covering licensed products, and expiration of all data exclusivity relating to the licensed products. Carina Biotech may terminate this agreement without cause on 90 days' written notice. Either party may terminate the agreement for cause in the event of the other party's insolvency or on 30 days' notice in the event of the other party's material breach of the agreement. In the event that a party terminates the agreement, the license granted to Carina Biotech will be terminated, and Carina Biotech will cease its development and exploitation of the licensed products except that Carina Biotech will have the right for 18 months to sell any inventory of licensed products existing as of the termination date.

In January 2023, Carina announced that it had received an FDA "Safe to Proceed" Letter for a Phase 1/2a clinical trial of BNC101 CAR-T therapy for the treatment of advanced colorectal cancer. In December 2023, Carina announced that patient dosing for their Phase 1/2a study had commenced. On October 30, 2024, Carina Biotech made a milestone payment to the Company in the gross amount of A$1 million under the terms of the Carina Biotech License agreement. The milestone payment was due to the Company as Carina Biotech achieved the initiation (i.e., first dosing in a human subject) of the first Phase 1 Clinical Trial with next-generation LGR5 stem cell antigen CAR-T technology (CNA3103) targeting solid tumors.

Research and License Agreement with Ironwood Pharmaceuticals

In January 2012, we entered into a research and license agreement with Ironwood Pharmaceuticals, Inc. ("Ironwood"), pursuant to which Ironwood was granted worldwide development and commercialization rights for BNC210. In November 2014, the parties mutually agreed to terminate this license agreement, reverting all rights to BNC210 back to us. The sole obligation to Ironwood is to pay Ironwood low to mid-single digit royalties on the net sales of BNC210, if commercialized.

Intellectual Property

Central Nervous System

As of June 30, 2025, we owned over 15 issued U.S. patents, one pending U.S. patent applications, two pending Patent Cooperation Treaty ("PCT") applications, over 30 granted foreign patents, and over 10 pending foreign patent applications in our central nervous system intellectual property portfolio.

With regard to our BNC210 product candidate, we own:

- one patent family with claims directed to the compositions of matter of BNC210, methods of preparing BNC210, and methods of treating anxiety and depressive disorders using BNC210, which are expected to expire in, 2027, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable; this family includes patents granted in the U.S. as well as Australia, Canada, France, Germany, the United Kingdom, and Japan.

- one patent family with claims directed to the manufacture and method of preparing BNC210, which are expected to expire in 2032, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable; this family includes patents granted in the U.S. as well as Australia, Canada, the United Kingdom, Germany, and Japan;

- one patent family with claims directed to the crystalline form of BNC210, which are expected to expire in 2033, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable; this family includes patents granted in the U.S. as well as Australia, Canada, the United Kingdom, Germany, France, Mexico, New Zealand and Hong Kong;

•one patent family with claims directed to the salts, cocrystal and polymorphic form of BNC210, which are expected to expire in 2034, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable; this family includes granted patents in the U.S. and Australia;

•one patent family with claims directed to solid form formulations of BNC210. The patent and patent applications claiming priority to this PCT application, if issued, are expected to expire in 2040, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable; this family includes a patent granted in China and a patent granted in the U.S., as well as multiple patent applications currently pending in Canada, China, Europe, Japan, Korea, Mexico, New Zealand, Israel and Australia; and

•two provisional applications filed with claims directed toward methods of treating social anxiety disorder and post trauma stress disorder.

We also have two patent families with claims directed to the composition of matter and their uses for the treatment of cognitive deficits and negative symptoms in schizophrenia and for the treatment of autism spectrum disorders, and are currently granted in US, Europe and Australia; and are pending in the Japan, Canada, and New Zealand. Patents issuing from such applications, if any, are expected to expire in 2039, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable.

Oncology

As of June 30, 2025, we owned over 8 issued U.S. patents, one pending U.S. patent application, and over 8 granted foreign patents, in our oncology intellectual property portfolio.

With regard to our BNC101 product candidate, we own three patent families with claims directed to compositions of matter and various methods of treatment using BNC101, with granted patents in the U.S., Australia, France, Germany, Japan, China, India, Korea, New Zealand and Hong Kong, with expiration dates ranging from 2033 to 2039, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable.

We strive to protect the proprietary technology that we believe is important to our business, including our drug candidates and our processes. We seek patent protection in the United States and internationally for our drug candidates, their methods of use and processes of manufacture and any other technology to which we have rights, where available and when appropriate. We also rely on trade secrets that may be important to the development of our business.

Our success will depend on the ability to obtain and maintain patent and other proprietary rights in commercially important technology, inventions and know-how related to our business, the validity and enforceability of our patents, the continued confidentiality of our trade secrets as well as our ability to operate without infringing the patents and proprietary rights of third parties. We rely on continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may own or license in the future, nor can we be sure that any of our existing patents or any patents we may own or license in the future will be useful in protecting our technology. For this and more comprehensive risks related to our intellectual property, please see "Risk Factors—Risks Relating to Protecting Our Intellectual Property." The term of an individual patent depends upon the legal term of the patent in the country in which it is obtained. In most countries in which we file, the patent term is 20 years from the date of filing the non-provisional priority application. Because any regulatory approval for a drug often occurs several years after the related patent application is filed, the resulting market exclusivity afforded by any patent on our drug candidates and technologies will likely be substantially less than 20 years. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office ("USPTO") in granting a patent or may be shortened if a patent is terminally disclaimed over an earlier-filed patent. The term of a U.S. patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. A patent term extension of up to five years may be granted beyond the expiration of the patent. This period is generally one-half of the time between the effective date of an IND (falling after issuance of the patent), and the submission date of an NDA, or BLA, plus the time between the submission date of an NDA and the approval of that application, provided the sponsor acted with diligence. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval and only one patent applicable to an approved drug may be extended. The application for patent term extension is subject to approval by the USPTO in conjunction with the FDA. Due to the specific requirements for obtaining these adjustments and extensions, there is no assurance that our patents will be afforded adjustments or extensions even if we encounter significant delays in patent office proceedings or marketing and regulatory approval.

Inflation and Seasonality

Management believes inflation has not had a material impact on our operations or financial condition. Management further believes that our operations are not currently subject to seasonal influences due to our current lack of marketed products. Moreover, the targets of our drug candidates are not seasonal diseases. Accordingly, once we have marketed products, management does not expect that our business will be subject to seasonal influences.

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries and local jurisdictions, extensively regulate, and impose substantial and burdensome requirements upon companies involved in, among other things, the research, development, testing, manufacture, quality control, sampling, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of our product candidates. Any drug candidates that we develop must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in those foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. We, along with our vendors, contract research organizations and contract manufacturers, will be required to navigate the various preclinical, clinical, manufacturing and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our product candidates. The process of obtaining regulatory approvals of drugs and ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

In the United States, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), as amended, its implementing regulations and other laws. If we fail to comply with applicable FDA or other requirements at any time with respect to product development, clinical testing, approval or any other legal requirements relating to product manufacture, processing, handling, storage, quality control, safety, marketing, advertising, promotion, packaging, labeling, export, import, distribution, or sale, we may become subject to administrative or judicial sanctions or other legal consequences. These sanctions or consequences could include, among other things, the FDA's refusal to approve pending applications, issuance of clinical holds for ongoing studies, withdrawal of approvals, warning or untitled letters, product withdrawals or recalls, product seizures, relabeling or repackaging, total or partial suspensions of manufacturing or distribution, injunctions, fines, civil penalties or criminal prosecution.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests, animal studies and formulation studies in accordance with good laboratory practice ("GLP"), requirements and other applicable regulations;
- submission to the FDA of an an Investigational New Drug Application ("IND") application, which must become effective before clinical trials may begin;
- approval by an Institutional Review Board ("IRB") or independent ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with applicable IND regulations, good clinical practice ("GCP") requirements and other regulations, to establish the safety and efficacy of the investigational product for its intended use;
- submission to the FDA of an NDA, after completion of all pivotal trials;
- a determination by the FDA within 60 days of its receipt of an NDA, to accept the filing for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug will be produced to assess compliance with current good manufacturing practice ("cGMP") requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA;
- payment of user fees for FDA review of the NDA; and
- FDA review and approval of the NDA to permit commercial marketing or sale of the drug for particular indications for use in the United States.

Preclinical Studies and Clinical Trials for Drugs

Before testing any drug in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of drug chemistry, formulation and stability, as well as *in vitro* and animal studies to assess safety and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP requirements for safety/toxicology studies. The results of the preclinical studies, together with manufacturing information and analytical data must be submitted to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before clinical trials may begin. Some long-term preclinical testing may continue even after the IND is submitted. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research patients will be exposed to unreasonable health risks, and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial or to commence a clinical trial with the investigational plan originally specified in the IND. Clinical trials involve the administration of the product candidate to human subjects under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirements that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters and criteria to be used in monitoring safety and evaluating effectiveness. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development, and for any subsequent amendments to the protocol. Furthermore, an IRB for each institution at which the clinical trial will be conducted must review and approve the plan for any clinical trial and its informed consent form before the trial begins at that site and must monitor the study until completed. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to the anticipated benefits. Regulatory authorities, including the FDA, as well as the IRB or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Information about applicable clinical trials, including clinical trial results, must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the trial was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary. Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined.

- Phase 1 - Phase 1 clinical trials involve initial introduction of the investigational product into healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- Phase 2 - Phase 2 clinical trials typically involve administration of the investigational product to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages, dose tolerance and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3 - Phase 3 clinical trials typically involve administration of the investigational product to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA.

•Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the approved indication. In certain instances, such as with accelerated approval drugs, FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points are generally prior to submission of an IND, at the End-of-Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor to obtain the FDA's feedback on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, manufacturers must develop methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life. While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA. Written IND safety reports must be submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human volunteers and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

DEA Regulation

The Controlled Substances Act ("CSA") establishes registration, security, recordkeeping, reporting, storage, distribution and other requirements that are administered by the Drug Enforcement Administration (DEA). DEA regulates the handlers of controlled substances, as well as the equipment and raw materials used in their manufacture and packaging, to prevent loss and diversion into illicit channels of commerce.

DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no currently accepted medicinal use, a high potential for abuse, and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular facility, the activities conducted at the facilities, and relevant controlled substance schedules. For example, separate registrations are required for a facility that both imports and manufactures a controlled substance, and each registration will specify which schedules of controlled substances are authorized.

DEA may inspect a facility to review its security measures prior to issuing a registration and may also conduct periodic inspections of registered establishments that handle controlled substances. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Records must be maintained for the handling of all controlled substances, and periodic reports made to DEA, for example distribution reports for Schedule I and II controlled substances, Schedule III substances that are narcotics, and other designated substances. Reports must also be made for thefts or losses of any controlled substance, and to obtain authorization to destroy any controlled substance. In addition, authorization and notification requirements apply to imports and exports.

A DEA quota system controls and limits the availability and production of controlled substances in Schedules I and II. Distributions of any Schedule I or II controlled substance must also be accompanied by order forms, with copies provided to DEA. DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although DEA has substantial discretion in whether or not to make such adjustments.

Individual states also regulate controlled substances.

U.S. Review and Approval Process for Drugs

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of an NDA must be obtained before a drug may be marketed in the United States. The submission of an NDA is subject to the payment of substantial user fees. The FDA adjusts the Prescription Drug User Fee Act ("PDUFA") user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure the product's continued safety, quality and purity. Under the goals and polices agreed to by the FDA under the PDUFA, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission (and a goal of six months for a priority review). This review typically takes twelve months for a standard NDA and eight months for a priority NDA from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after the application is submitted. Specifically, the FDA conducts a preliminary review of all submitted NDAs within 60 days of receipt to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. The FDA does not always meet its PDUFA goal dates for standard or priority NDAs, and the review process is often extended by FDA requests for additional information or clarification.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which 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 manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP and other requirements and the integrity of the clinical data submitted to the FDA.

If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

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

If regulatory approval of a product is granted, such approval will be granted for particular indications and may contain limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a Risk Evaluation and Mitigation Strategy ("REMS") to ensure that the benefits of the drug outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, assessment plans and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk-minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may also require one or more post-approval

studies and surveillance, including Phase 4 clinical trials, be conducted to further assess and monitor the product's safety and effectiveness after marketing, and may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some 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. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

Expedited Development and Review Programs for Drugs

The FDA has a number of programs intended to expedite the development or review of products that meet certain criteria.

For example, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for such disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a Fast Track designated product has opportunities for more frequent sponsor interactions with the FDA review team during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed, meaning that the agency may review portions of the marketing application before the sponsor submits the complete application, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. In addition, a sponsor may seek FDA designation of a product candidate as a "breakthrough therapy" if the product candidate is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to more intensive FDA interaction and guidance. If a product is designated as Breakthrough Therapy, the FDA will work to expedite the development and review of such drug through FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for other types of FDA programs intended to expedite development and review, including Priority Review designation and Accelerated Approval. A product is eligible for Priority Review if it has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Under priority review, the FDA targets reviewing an application in six months after filing compared to ten months after filing for a standard review.

Additionally, products may be eligible for Accelerated Approval if they are intended to treat serious or life-threatening diseases or conditions and are determined to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality which is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving Accelerated Approval conduct additional post-approval studies to verify and describe the product's clinical benefit. The FDA may withdraw approval of a drug or indication approved under Accelerated Approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, for products reviewed under Accelerated Approval, unless otherwise informed by the FDA, the FDA requires that all advertising and promotional materials that are intended for dissemination or publication within 120 days following marketing approval be submitted to the agency for review during the pre-approval review period, and that after 120 days following marketing approval, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.

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 the time period for FDA review or approval may not be shortened. Furthermore, Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval do not change the standards for approval but may expedite the development or review process. We may explore some of these opportunities for our product candidates as appropriate.

Pediatric Information and Pediatric Exclusivity

Under the Pediatric Research Equity Act ("PREA"), as amended, certain NDAs and certain supplements to an NDA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The FD&C Act requires that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan ("PSP"), within 60 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 trial. 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 preclinical studies, early phase clinical trials and/or other clinical development programs.

A drug can also obtain pediatric market exclusivity in the U.S. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial or of multiple pediatric trials in accordance with an FDA-issued "Written Request" for such trials.

U.S. Post-Approval Requirements for Drugs

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, reporting of adverse experiences with the product, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. 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 program fees for any marketed products.

In addition, drug manufacturers and their subcontractors involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon us and our contract manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. Failure to comply with statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution.

The FDA may withdraw 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, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- fines, warning letters or untitled letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or withdrawal of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and issuance of corrective information; and
- injunctions or the imposition of civil or criminal penalties.

The FDA may also require post-market testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. The FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their

independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labeling. In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act ("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.

Marketing Exclusivity

Market exclusivity provisions under the FD&C Act can delay the submission or the approval of certain marketing applications. The FD&C Act provides a five-year period of non-patent exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if 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. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application ("ANDA"), or an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication. However, such an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FD&C Act alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities of product candidates following product approval, where applicable, or commercialization are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, which may include the Centers for Medicare & Medicaid Services other divisions of the HHS, the Department of Justice, the DEA, the Consumer Product Safety Commission, the Federal Trade Commission ("FTC"), the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

Other Healthcare Laws

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business and may constrain the financial arrangements and relationships through which we research, sell, market and distribute any products for which we obtain marketing approval. Such laws include, without limitation, federal and state anti-kickback, fraud and abuse, false claims, and transparency laws and regulations with respect to drug pricing and payments and other transfers of value made to physicians and other health care providers. Violations of any of such laws or any other governmental regulations that apply may result in significant penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations to resolve allegations of noncompliance, exclusion from participation in federal and state healthcare programs and imprisonment for any responsible individuals.

Coverage and Reimbursement

Our ability to successfully commercialize any pharmaceutical product candidate depends, in part, on (1) the extent to which the product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and (2) the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Even if

coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

Third-party payors are increasingly reducing coverage and reimbursement for medical products, drugs and services. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products; and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. In addition, 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, adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

Healthcare Reform

In the United States, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, as amended, collectively known as the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and changes to fraud and abuse laws. For example, the ACA:

- increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and
- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 2024. Further, in August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030.

Further, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law, which marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (began in 2023), and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated, and while the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

On July 4, 2025, the One Big Beautiful Bill Act (OBBBA) was signed into law and, which is believed will significantly affect biotech companies, including tax incentives that benefit biotech innovation. The OBBBA also restores the ability for companies to immediately deduct domestic research and experimentation costs, a provision that was previously phased out. This change provides significant tax relief and increases cash flow for biotech and life sciences companies, especially small and early-stage companies. Additionally, OBBBA amends the Inflation Reduction Act to be more favorable for orphan drug developers by allowing a drug with multiple orphan designations to remain exempt from price negotiation, potentially preserving profitability for rare disease therapies.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has already resulted in several Congressional inquiries, proposed and enacted legislation and executive orders 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. This has more recently led the Federal Trade Commission and the Department of Justice to begin investigating whether some pricing algorithms facilitate illegal price-fixing by relying on competitor pricing data. Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical 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.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could impact the amounts that federal and state governments and other third-party payors will pay for healthcare products and services.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality, and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including Health Insurance Portability and Accountability Act ("HIPAA") and federal and state consumer protection laws and regulations (e.g., Section 5 of the Federal Trade Commission Act) that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, certain state and non-U.S. laws, such as the California Consumer Privacy Act ("CCPA"), the California Privacy Rights Act ("CPRA"), Australia's Privacy Act 1988, as amended, and the General Data Protection Regulation ("GDPR") govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to make compliance efforts more challenging, and can result in investigations, proceedings, or actions that lead to significant penalties and restrictions on data processing.

Employees

As of June 30, 2025, we had a total of seven full-time employees, one part-time employee, and sixteen part-time consultants. None of our employees are represented by any collective bargaining agreements. We believe that we maintain good relations with our employees. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of share-based compensation awards and cash-based performance bonus awards.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of share-based compensation awards and cash-based performance bonus awards.

Item 1A. Risk Factors.

The following risk factors apply to the business and operations of Neuphoria and its consolidated subsidiaries. Our business, financial condition or results of operations could be materially and adversely affected by the occurrence of one or more of the events or circumstances described in these risk factors, alone or in combination with other events or circumstances, and may have an adverse effect on our business, financial condition and results of operations. We may face additional risks and uncertainties that are not presently known to us or that we currently deem immaterial, which may also impair our business, cash flows, financial condition and results of operations. You should carefully consider the risks described below and elsewhere in this Annual Report on Form 10-K before making an investment decision. The following risk factors are not the only risk factors facing the Company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business.

Risks Related to Our Financial Condition and Capital Requirements

We are a clinical-stage biopharmaceutical company with no approved products. We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical company and commenced operations in 1996. To date, we have focused primarily on performing research and development activities, establishing our intellectual property portfolio (including acquisitions, in-licensing and out-licensing), discovering potential product candidates, conducting preclinical studies and clinical trials and raising capital. Our approach to the discovery and development of product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value. Our lead CNS product candidate, BNC210, is in clinical development, and our additional wholly owned CNS development programs remain in the preclinical or discovery stage. There is no guarantee that we will be able to continue the development of or advance any product candidate into further clinical trials or meet the capital requirements necessary to further conduct such activities. We have no products approved for commercial sale and we have not yet demonstrated an ability to successfully obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization. Consequently, we cannot and do not make any predictions about our future success or viability as we have not had a history of successfully developing and commercializing biopharmaceutical products to date.

We have incurred significant operating losses since our inception. If our product candidates are not successfully developed and approved, we may never generate any revenue. Our total accumulated deficit was $178.3 million for the fiscal year ended June 30, 2025. Substantially all our losses have resulted from expenses incurred in connection with our research and development programs, preclinical studies, clinical trials and from general and administrative costs associated with our operations. Our product candidates will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from such product sales, if any. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we conduct our ongoing and planned preclinical studies and clinical trials, initiate and scale our production capacity, seek regulatory approvals for our product candidates, hire additional personnel, obtain and protect our intellectual property, initiate further research and development and incur additional costs for commercialization or to expand our pipeline of product candidates.

To become and remain profitable, we must succeed in developing and eventually commercializing, licensing and/or acquiring products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of some of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Even if we do achieve profitability, we may not be able to sustain or increase profitability. If we fail to become and remain profitable, the value of our common stock could be depressed and our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates or continue our operations could be impaired, and some or all the value of our common stock could be lost.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.

The development of biopharmaceutical product candidates is capital intensive. Since our inception, we have used substantial amounts of cash to fund our operations and we expect our expenses to increase in connection with our ongoing activities during the next several years, particularly as we conduct our ongoing and planned and future clinical trials of BNC210, continue research and development for any additional product candidates, and seek regulatory approval for our current product candidates and any future product candidates we may develop. In addition, if, following approval, we commercialize BNC210 or any other product candidates, we may need to make royalty or other payments to our licensors and other third parties. Further, in connection with the termination of our previous research and license agreement with Ironwood Pharmaceuticals, Inc. ("Ironwood"), we are obligated to pay Ironwood a low to mid-single digit royalty on the net sales of BNC210, if commercialized. Furthermore, if and to the extent we seek to acquire or in-license additional product candidates or rights in the future, we may be required to make significant upfront payments, milestone payments, licensing payments, royalty payments and/or other types of payments. If we obtain regulatory approval for any of our product candidates, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Because the outcome of any clinical trial or preclinical study is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates. Furthermore, we have incurred and expect to continue to incur significant costs associated with operating as a U.S. public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital or find alternative sources of financing when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs, clinical trials or any future commercialization efforts.

We had cash and cash equivalents of $14.2 million as of June 30, 2025. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other capital sources, including potentially collaborations, licenses and other arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. The volatility of the capital markets, domestically and internationally, the impact of inflation and interest rates on the general economy, and economic downturns that are out of our control may affect the availability, amount and type of financing available to us in the future. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates.

Our future financing requirements will depend on many factors, including:

- the type, number, scope, progress, expansions, results, costs and timing of our clinical trials (especially if and as we move into Phase 3 clinical trials) and preclinical studies of our product candidates which we are pursuing or may choose to pursue in the future;
- safety concerns related to the use of our product candidates;
- adverse findings regarding the efficacy of our product candidates as additional information is acquired;
- the costs and timing of manufacturing for our product candidates, including commercial manufacturing if any product candidate is approved;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of jurisdictions in which we plan to seek regulatory approvals;
- the costs of obtaining, maintaining, enforcing and defending our patents and other intellectual property and proprietary rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a U.S. public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our clinical activities increase;
- the timing and amount of the royalty or other payments we must make to our licensors and other third parties;
- the timing and amount of milestone or royalty payments we receive from out-licensees, such as Merck, Australian Cooperative Research Centre for Cancer Therapeutics ("CTx"), or Carina;
- the costs and timing of establishing or securing sales and marketing capabilities if any product candidate is approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and
- costs associated with any product candidates, products or technologies that we may in-license or acquire.

Conducting clinical trials (especially if and as we move into Phase 3 clinical trials, which are typically substantially more expensive and of longer duration) and preclinical studies is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all.

Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs, future commercialization efforts or other operations.

Raising additional capital may cause dilution to our shareholders, including holders of our common stock, restrict our operations, or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial revenues, we expect to finance our business and operational needs through equity offerings, debt financings or other financing sources, including potentially collaborations, licenses and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, investors' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect investors' rights as a holder of our common stock. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through future collaborations, licenses and other similar arrangements, we may have to relinquish valuable rights to our future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock. We may also lose control of the development of our products or product candidates, such as the pace and scope of clinical trials, as a result of such third-party arrangements. If we are unable to raise funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

For example, on May 31, 2024, we entered into a Securities Purchase Agreement with a select institutional accredited investor, pursuant to which the Company agreed to issue and sell to the Investor in a three-tranche private placement (the "Private Placement") of American Depositary Shares ("ADS") , and an accompanying five year cash purchase warrant (the "Accompanying Warrant," related solely to the first tranche of the private placement). The first tranche of the Private Placement consisted of 1,296,486 ADSs (equal to 108,040 shares of common stock post December 2024 redomiciliation) and a 6,279,905 Pre-Funded Warrant (or 523,325 shares of common stock post December 2024 redomiciliation). The first tranche of the private placement closed on June 3, 2024, resulting in aggregate gross proceeds to the Company of $7.5 million.

Sales of Common Stock issuable upon exercise of the Warrant and other derivative securities could cause the market price of our Common Stock to decline.

If we issue warrant(s), then such warrant(s) will entitle the holder to receive additional securities from us, diluting your ownership interest. For example, in the Private Placement offering that we consummated in June 2024, the warrants issued in the first tranche of that offering entitled the investor to purchase up to an aggregate of 18,932,477 ADSs (or 1,577,706 shares of common stock on a post redomiciliation basis), of which a 6,279,905 Pre-Funded Warrant (or a Pre-Funded Warrant exercisable for 523,325 shares of common stock on post redomiciliation basis) had been issued. The sale of additional shares of common stock or warrant, or the perception that such sales could occur, could cause the market price of our common stock to decline or become more volatile.

Sales of a substantial number of our shares of Common Stock by significant existing shareholders in the public market, or the perception that such sales may occur, could depress the trading price of our shares of Common Stock.

Sales of a substantial number of our shares of common stock or securities exercisable or convertible into common stock in the public market or the perception that these sales may occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital.

In particular, on May 31, 2024, prior to our redomiciliation, we had entered into a Securities Purchase Agreement with Armistice Capital Master Fund Ltd. ("Armistice") pursuant to which the Company agreed to issue and sell in the above described Private Placement a certain number of restricted ADSs, a pre-funded warrant to purchase ADSs and an accompanying 5-year cash purchase warrant ("Accompanying Warrant").

In connection with the first tranche of the Private Placement, we issued an Accompanying Warrant to purchase up to 12,652,572 ADSs (equal to 1,054,381 shares of common stock post redomiciliation at an exercise price of US$11.88 per share) (or pre-funded warrant in lieu thereof), which Accompanying Warrant remains issued and outstanding as of the date of this Annual Report. The Accompanying Warrant is immediately exercisable and remains exercisable until June 2, 2029. However, Armistice may not exercise the Accompanying Warrant to the extent such exercise would cause it to beneficially own a number of shares of common stock that would exceed 4.99% of our then outstanding shares of common stock following such exercise.

The trading price of our shares of common stock has been volatile, and holders of our common stock may not be able to resell the shares of common stock at or above the price paid.

The trading price of our common stock on the Nasdaq Global Market has been highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include but are not limited to the "Risk Factors" noted below and as set forth in our Annual Report and positive, negative or unexpected developments relating to:

- results from, or any delays in, clinical trial programs relating to our product candidates;
- our ability to obtain regulatory approval for our product candidates, or delays in obtaining such approval;
- our ability to commercialize any future drugs, or delays in commercializing such drugs;
- announcements of regulatory approval or a complete response letter to our product candidates, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- the timing and amount of payments to us under our collaborations, if any;
- announcements of therapeutic innovations or new drugs by us or our competitors;
- announcements regarding the parent drugs that we use in developing our product candidates;
- actions taken by regulatory authorities with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to our product candidates;
- any changes to our relationship with any manufacturers or suppliers;
- the success of our testing and clinical trials;the success of our efforts to acquire or license or discover additional product candidates;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected drug sales and profitability;
- manufacture, supply or distribution shortages;
- actual or anticipated fluctuations in our operating results;
- the FDA, EMA or other similar regulatory actions affecting us or our industry or other healthcare reform measures in the United States or elsewhere;
- changes in financial estimates or recommendations by securities analysts;
- trading volume of our common stock;
- sales of our common stock or other securities by us, our senior management and directors or our shareholders in the future;
- general economic and market conditions and overall fluctuations in the equity markets; and
- the loss of any of our key scientific or senior management personnel.

In addition, the stock markets in general, and the markets for biotechnology and pharmaceutical stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our shareholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our senior management

would be diverted from the operation of our business, which could seriously harm our financial position. Any adverse determination in litigation could also subject us to significant liabilities.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and results of operations and the price of our common stock.

From time to time, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that future deterioration in credit and financial markets and confidence in economic conditions will not occur. Our business strategy and performance may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine, conflicts in the Middle East, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, trade disputes, illegal immigration, drug trafficking and more may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. If the current equity and credit markets deteriorate or become illiquid, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business, financial condition and results of operations and the price of our common stock.

If we fail to meet the continued listing requirements of Nasdaq, it could result in a de-listing of our Common Stock.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements, continued listing requirements such as the minimum $1.00 closing bid price requirement, Nasdaq could take steps to delist our common stock. Any failure by us to comply with Nasdaq's continued listing standards could result in a deficiency notice and, if not cured within the applicable period, could result in delisting. Our shares of common stock are currently listed on the Nasdaq Global Market. While we have always strived to maintain full compliance with applicable Nasdaq listing standards, we have in the past received notices of non-compliance, which we have addressed and successfully resolved. For example, On July 18, 2025, the Company received a deficiency notification letter (the "Notice") from the Listing Qualifications Staff of The Nasdaq Stock Market LLC ("Nasdaq"). The Notice indicated that the Company was not in compliance with Nasdaq Listing Rule 5620(a) (the "Listing Rule") as a result of the Company's failure to hold an annual meeting of stockholders within twelve months of the end of the Company's fiscal year ended June 30, 2024. The Listing Rule requires that a Nasdaq-listed company hold an annual meeting of shareholders no later than one year after the end of the company's fiscal year end. While the Company had held a substantial shareholder meeting in December 2024, in part to obtain approval related to its redomicilation as a Delaware corporation, to remedy the July non-compliance notice from Nasdaq, the Company plans to hold its 2025 annual general shareholder meeting on or about November or December 2025, in-line with past annual shareholder meeting dates, in satisfaction of the compliance item provided in the Notice.

The Company timely submitted its written plan to Nasdaq to regain compliance with the Listing Rule. Pursuant to the Notice, if Nasdaq accepts the Plan, Nasdaq has the discretion to grant the Company an exception of up to 180 calendar days (the "Compliance Period") from the end of the Company's fiscal year, or until December 29, 2025, to regain compliance with the Listing Rule. The Notice has no immediate effect on the listing of the Company's common stock on Nasdaq in the interim.

It should be noted, however, that any future Nasdaq action relating to a delisting could have a negative effect on the price of our common stock, impair the ability to sell or purchase our common stock or other securities when persons wish to do so, and any such delisting action may materially adversely affect our ability to raise capital or pursue strategic restructuring, refinancing or other transactions on acceptable terms, or at all. Delisting from the Nasdaq Global Market could also have other negative results, including the potential loss of institutional investor interest, reduced research coverage, and fewer business development opportunities.

An active, liquid trading market for our common stock may not be maintained.

We can provide no assurance that we will be able to maintain an active trading market for our common stock. The lack of an active market may impair the ability of any investor to sell our common stock at the time an investor may wish to sell them or at a price that an investor may consider reasonable. An inactive market may also impair our ability to raise capital by selling securities and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business.

We are not currently paying dividends and will likely continue not paying cash dividends on our common stock for the foreseeable future.

We have not in the past and do not anticipate paying any cash dividends on our common stock for the foreseeable future. Investors should not rely on an investment in us if they require income generated from dividends paid on our capital stock. Any income derived from our common stock may only come from a rise in the market price of our common stock, which is uncertain and unpredictable.

We are an "emerging growth company" (as defined in the JOBS Act) and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and any proxy statements, exemptions from the requirements of holding a non-binding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We have also elected to rely on an exemption that permits an emerging growth company to include only two years of audited financial statements and only two years of related management's discussion and analysis of financial condition and results of operations disclosure, and we have therefore only included two years of audited financial statements, selected financial data and management's discussion and analysis of financial condition and results of operations in this Annual Report. We cannot predict if investors will find our common stock less attractive because 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 the trading price of our common stock may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock shares that are held by non-affiliates to exceed $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

We incur significant costs as a result of operating as a U.S. listed public company and our management is required to devote substantial time and expense to various compliance issues.

As a publicly-traded company in the United States, and particularly if we cease to be an "emerging growth company" as defined in the JOBS Act, we continue to and will incur substantial legal, accounting and other expenses as a result of the reporting requirements of the Exchange Act. In addition, Sarbanes-Oxley Act, along with rules promulgated by the SEC, and Nasdaq, where our common stock trades, have significant requirements on public companies, including many changes involving corporate governance. Management and other company personnel devote a substantial amount of time ensuring our compliance with these regulations. Accordingly, our legal, accounting and financial compliance expenses have significantly increased, and certain corporate actions have become more time-consuming and costly. For example, these regulations have made it more difficult to attract and retain qualified members of our board of directors and various corporate committees. Obtaining director and officer liability insurance is significantly more expensive as a public company.

If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our commons stock adversely, the trading price and volume of our Common Stock could decline.

The trading market for our common stock are influenced by the research reports and opinions that securities or industry analysts publish about our business. Investors have numerous investment opportunities and may limit their investments to publicly traded companies that receive thorough research coverage. If no analysts cover us or if one or more analysts cease to cover us or fail to publish reports in a regular manner, we could lose visibility in the financial markets, which could cause a significant and prolonged decline in the trading price of our common stock due to lack of investor awareness.

In the event that we do not obtain analyst coverage, or if one or more of the analysts downgrade our common stock or comment negatively about our prospects or the prospects of other companies operating in our industry, the trading price of our common stock could decline significantly. There is no guarantee that equity research organizations will elect to initiate or sustain research coverage of us, nor whether such research, if initiated, will be positive towards the trading price of our common stock or our business, financial condition, results of operations and prospects.

As a U.S. public reporting company, we are required to maintain effective internal control over financial reporting suitable to prepare our publicly reported financial statements in a timely and accurate manner.

Pursuant to Section 404 of Sarbanes-Oxley, our management is required to report upon the effectiveness of our internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our

internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we will need to upgrade our information technology systems, implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff. If we or, if required, our auditor is unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our ADSs may decline.

Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. For as long as we remain an emerging growth company, we intend to take advantage of the exemption permitting us not to comply with the independent registered public accounting firm attestation requirement. When we lose our status as an "emerging growth company" and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting.

We cannot be certain as to when we will be able to implement the requirements of Section 404 of the Sarbanes-Oxley Act. Any failure to implement these requirements in a timely manner or to maintain internal control over our financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We may become involved in securities class action litigation that could divert management's attention and adversely affect our business and could subject us to significant liabilities.

The stock markets have, from time to time, experienced significant price and volume fluctuations that have affected the market prices for the shares of biotechnology and pharmaceutical companies. These broad market fluctuations as well a broad range of other factors, including the realization of any of the risks described in the "Risk Factors" section of this Annual Report, may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies generally experience significant share price volatility. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

Our financial statements in prior years had been prepared assuming a going concern.

Our financial statements as of June 30, 2025 were prepared under the assumption that we will continue as a going concern for the next twelve months from the date of issuance of these financial statements. In the past we had a going concern qualification and there can be no assurances that in the future we will not have a going concern qualification. Our ability to continue as a going concern has in the past been dependent upon our ability to obtain additional financing, obtain further operating efficiencies, reduce expenditures and ultimately, create profitable operations. If factors arise that create substantial doubt about our ability to continue as a going concern, we would be required to report such.

Our operating results have fluctuated significantly in the past and may continue to do so in the future, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our operating results have fluctuated significantly in the past and may continue to do so in the future. Fluctuations in our operating results may occur due to a variety of factors, many of which are out of our control and may be difficult to predict, including:

- the timing and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to our product candidates, which may change from time to time;
- the timing of milestone payments, if any, under our license and collaboration agreements;
- the timing and amount of royalty or other payments, if any, under our license and collaboration agreements;
- expenditures that we may incur to acquire, develop, or commercialize additional product candidates and technologies;

- the level of demand for our current or future product candidates, if approved, which may vary significantly;
- coverage and reimbursement policies with respect to our product candidates, if approved, and existing and potential future drugs that compete with our product candidates;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with third-party manufacturers;
- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation of our competitors or partners;
- the timing and exercise, if any, of outstanding warrant and options;
- foreign currency fluctuations; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our operating results. As a result, comparisons of our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any guidelines we may provide to the market, or if the guidelines we provide to the market are below the expectations of analysts or investors, this could adversely affect the trading price of our common stock. Such a decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

If we lose research and development incentives from the Australian government, then we could encounter difficulties in funding future research and development projects, which could harm our operating results.

We have historically received cash incentives through the Australian Government's Research and Development Tax Incentive program, under which the Australian Government currently provides a refundable tax offset, payable as a cash incentive, of up to 43.5% of eligible approved research and development expenditures by Australian entities with an "aggregated turnover" of less than A$20 million and an additional tax deduction of 8.5 to 16.5% of eligible approved research and development expenditures if "aggregated turnover" is greater than A$20 million.

For the fiscal years ended June 30, 2025 and 2024, we recognized a refundable tax offset of approximately $300,000 and $95,000, respectively. Entitlement to tax offsets under the Research and Development Tax Incentive for eligible research and development purposes is based on an annual application to the Australian Government. For overseas activities that have a significant scientific link to the Australian activities, the expenditure in Australia needs to be greater than the expected overseas expenditure to be eligible.

In the event of our research and development expenditures being deemed "ineligible," then our incentives would decrease, and our future cash flows would be negatively affected. In addition, the Australian Government may modify the requirements of, reduce the amounts of the tax offset entitlement under, or discontinue the Research and Development Tax Incentive program. If the Research and Development Tax Incentive program was discontinued, or if the tax incentive rate was reduced, it would have a negative effect on the size of future refundable tax offsets and our future cash flows.

Our ability to utilize our tax losses and certain other tax attributes may be limited.

We have substantial carried forward tax losses, which may not be available to offset future gains, if any. In order for an Australian corporate taxpayer to carry forward and utilize tax losses, the taxpayer must pass either the "continuity of ownership test" or, if it fails such test, the "business continuity test" in respect of relevant tax losses. We have not carried out any analysis as to whether we have met the continuity of ownership test or, failing such test, the business continuity test over relevant periods. In addition, shareholding changes may result in a significant ownership change for us under Australian tax law. It is therefore uncertain whether any of our losses carried forward as of June 30, 2025 will be available to be carried forward and available to offset our assessable income, if any, in future periods.

Inflation could adversely affect our business and results of operations.

While inflation in the United States had been relatively low for a number of years through 2020, beginning in 2021 and continuing today, the economy in the United States encountered a material level of inflation. While inflation has recently reduced, there is uncertainty whether inflation will continue and how long, and at what rate. Increases in inflation raise our costs for commodities, labor, materials and services and other costs required to grow and operate our business, and failure to secure these goods and services on reasonable terms may adversely impact our financial condition, operations and cash flows.

Risks Related to the Discovery, Development and Regulatory Approval of Our Product Candidates

Our preclinical and clinical programs may experience delays, unforeseen costs or may never advance, which could adversely affect our ability to obtain regulatory approvals or commercialize our product candidates on a timely basis or at all, which could have an adverse effect on our business and shareholder value.

In order to obtain FDA approval to market a new small molecule product, we must demonstrate the safety and efficacy of our product candidates in humans to the satisfaction of the FDA. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials.

Conducting preclinical testing and clinical trials is a lengthy, time-consuming and expensive process and is subject to uncertainty. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for product candidates in our industry is high. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are directly conducting preclinical studies and clinical trials may cause us to incur additional operating expenses. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including, for example:

- timely completion of preclinical laboratory tests, animal studies and formulation studies in accordance with FDA's good laboratory practice requirements and other applicable regulations;
- submission of an IND to the FDA and delays or failure in obtaining clearance thereof by the FDA;
- delays or failure in obtaining approval by an independent IRB or ethics committee at each clinical site before each trial may be initiated;
- delays in reaching a consensus with regulatory agencies on study design and obtaining regulatory authorization to commence clinical trials;
- delays in reaching agreement on acceptable terms with prospective contract research organizations ("CROs"), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, contracting and training suitable clinical investigators;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing;
- insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- imposition of a temporary or permanent clinical hold by regulatory authorities;
- developments on trials conducted by competitors for related technology that raises FDA or foreign regulatory authority concerns about risk to patients of the technology broadly, or if the FDA or a foreign regulatory authority finds that the investigational protocol or plan is deficient to meet its stated objectives;
- delays or failure in screening and enrolling suitable patients and delays or failure caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulties collaborating with patient groups and investigators;
- failure by our investigators and patients to adhere to clinical trial protocols;
- failure by our CROs, other third parties or us to manage the clinical trials according to the contracted terms and timelines;
- failure to perform clinical trials in accordance with the FDA's good clinical practice requirements ("GCPs"), or applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of adverse events in a trial of the same class of agents conducted by other companies;
- changes to the clinical trial protocols;
- clinical sites dropping out of a trial;
- changes in regulatory requirements and guidance including primary efficacy endpoints for approval that require amending or submitting new clinical protocols;

•changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;

•selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data;

•the cost of clinical trials of our product candidates being greater than we anticipate;

•inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;

•clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;

•transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization ("CMO"), and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and

•third parties being unwilling or unable to satisfy their contractual obligations to us.

Further, conducting clinical trials in foreign countries for our product candidates presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to the clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Delays or failure in the completion of any preclinical studies or clinical trials of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate product revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any delays to or failure in our preclinical studies or clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

We have entered Phase 3 of our development efforts for BNC210 in SAD and are preparing to enter into Phase 2b/3 of our development efforts for BNC210 in PTSD. If we are unable to commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

Our ability to become profitable depends upon our ability to generate revenue. To date we have not generated any sales revenue from our product candidates, and we do not expect to generate any revenue from the sale of drugs in the near future. We do not expect to generate revenue from product sales unless and until we complete the development of, obtain marketing approval for, and begin to sell, one or more of our product candidates. We are also unable to predict when, if ever, we will be able to generate revenue from such product candidates due to the numerous risks and uncertainties associated with drug development, including the uncertainty of:

•our ability to timely and successfully complete preclinical studies and clinical trials for BNC210 and other current or future product candidates;

•the ability of our existing or future licensees and collaborators to successfully develop and commercialize product candidates pursuant to collaboration agreements, including Merck with respect to its two product candidates and Carina with respect to BNC101;

•our successful initiation, enrollment in and completion of clinical trials for BNC210 and other current or future product candidates, including our ability to generate positive data from any such clinical trials;

•our ability to demonstrate to the satisfaction of the FDA and comparable regulatory authorities the safety, efficacy, consistent manufacturing quality and acceptable risk-benefit profile of our product candidates for their intended uses;

•our plans to submit NDAs to the FDA for BNC210 and future product candidates;

•our ability to obtain in a timely manner necessary approvals or authorizations from applicable regulatory authorities;

•the costs associated with the development of any additional development programs we identify in-house or acquire through collaborations or other arrangements;

•our ability to establish manufacturing capabilities or make arrangements with third-party manufacturers for clinical supply and commercial manufacturing;

•our ability to advance our early-stage CNS assets into IND-enabling studies either on our own or through collaborations;

•obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our current and future product candidates;

•launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;

•obtaining and maintaining acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;

•effectively competing with other therapies;

•obtaining and maintaining healthcare coverage and adequate reimbursement;

•the terms and timing of any additional collaboration, license or other arrangement, including the terms and timing of any payments thereunder;

•our ability to enforce and defend intellectual property rights and claims; and

•our ability to maintain continued acceptable safety profiles of our product candidates following approval.

We expect to incur significant sales and marketing costs as we prepare to commercialize our current or future product candidates. Even if we initiate and successfully complete pivotal or registration-enabling clinical trials of our current or future product candidates, and our current or future product candidates are approved for commercial sale, and despite expending these costs, our current or future product candidates may not be commercially successful. We may not achieve profitability soon after generating drug sales, if ever. If we are unable to generate revenue, we will not become profitable and may be unable to continue operations without continued funding.

If we experience delays or difficulties in the initiation, enrollment and/or retention of patients in clinical trials, our regulatory submissions or receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue our then ongoing or planned clinical trials on a timely basis or at all for our product candidates if we are unable to recruit, enroll and retain a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the U.S. Patient enrollment is a significant factor in the timing of clinical trials. Our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate.

Moreover, some of our clinical trials will compete with other companies' clinical trials that are in the same therapeutic areas as our current or future product candidates, and this competition reduces the number and types of patients available to us, as some patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' current or future product candidates. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. In addition, there may be limited patient pools from which to draw for clinical studies. In addition to the rarity of some diseases, the eligibility criteria of our clinical studies may further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a study.

Patient enrollment for any of our future clinical trials may be affected by other factors including:

•the size and nature of the patient population;

•competition with other companies for clinical sites or patients;

•the willingness of participants to enroll in our clinical trials in our countries of interest;

•the severity of the disease under investigation;

•availability and efficacy of approved drugs for the disease under investigation;

•the eligibility criteria for the clinical trial in question as defined in the protocol;

•the availability of an appropriate screening test(s) for the indications we are pursuing;

•the perceived risks and benefits of the product candidate under study in relation to other available therapies, including any new products that may be approved for the indications we are investigating;

•the efforts to facilitate timely enrollment in and completion of clinical trials;

•delays in or temporary suspension of the enrollment of patients in our then ongoing or future clinical trials in the event of a future pandemic;

•ability to obtain and maintain patient consents;

•the patient referral practices of physicians;

•the ability to monitor patients adequately during and after treatment;

•the proximity and availability of clinical trial sites for prospective patients; and

•the risk that patients enrolled in clinical trials will drop out of the trials before completion.

These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow-up periods.

Interim, topline or preliminary data from our preclinical studies and clinical trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, topline or preliminary data from our preclinical studies and clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Moreover, caution should be exercised in drawing any conclusions from a comparison of data that does not come from head-to-head analysis. As a result, the interim, topline or preliminary results that we report may differ from future results of the same studies or clinical trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim, topline or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, such data should be viewed with caution until the final data are available, as such interim, topline or preliminary data are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues and more participant data become available or as participants from our clinical trials continue other treatments for their disease. Adverse differences between preliminary, interim or topline data and final data could significantly harm our business prospects.

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and negatively impact the value of our ADSs. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and investors or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Results of earlier clinical trials may not be predictive of the results of later-stage clinical trials.

The results of preclinical studies and early clinical trials of our current and/or our other future product candidates, if any, including positive results, may not be predictive of the results of later-stage clinical trials. Each of our current or any other future product candidates in later stages of clinical development may fail to show the desired safety and efficacy results despite having progressed through nonclinical studies and initial clinical trials, as is the case for results from our BNC210 Phase 2 PREVAIL Study and Phase 2 ATTUNE Study. Many companies in the biopharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. Similarly, our future clinical trial results may not be successful for these or other reasons.

Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in nonclinical studies and clinical trials nonetheless failed to obtain FDA approval or approval from a similar regulatory authority in another country. With respect to our current product candidates, if our

current or future nonclinical or clinical studies fail to produce positive results, the development timeline and regulatory approval and commercialization prospects for these candidates and, correspondingly, our business and financial prospects, as well as the value of our securities, including our Ordinary Shares and ADSs, could be materially adversely affected.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our current or future product candidates, we will not be able to commercialize, or will be delayed in commercializing, our current or future product candidates, and our ability to generate revenue will be materially impaired.

Our current or future product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export, are subject to comprehensive regulation by the FDA and other regulatory agencies in the U.S. and by comparable authorities in other countries. Before we can commercialize any of our current or future product candidates, we must obtain marketing approval from the regulatory authorities in the relevant jurisdictions. We have not received approval to market any of our current or future product candidates from regulatory authorities in any jurisdiction, and it is possible that none of our current product candidates, nor any product candidates we may seek to develop in the future, will ever obtain regulatory approval. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our current or future product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. In addition, even if we believe that our trials demonstrate the safety and/or effectiveness of a product candidature, regulatory authorities may not agree with our interpretation of the results of our trials and conclude that the data are not adequate to support approval.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our current or future product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our drugs, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our current or future product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our current or future product candidates, the commercial prospects for our current or future product candidates may be harmed and our ability to generate revenues will be materially impaired.

Our current or future product candidates may cause adverse or other undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our current or future product candidates could cause us to interrupt, delay or halt preclinical studies or could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities for such products. It is likely that there may be adverse side effects associated with the use of our product candidates. To date, patients treated with BNC210 have experienced drug-related side effects including headaches, somnolence and nausea. There is also the potential risk of delayed adverse events following treatment using any of our current or future product candidates.

If unacceptable side effects arise in the development of our product candidates, we, the FDA, the IRBs at the institutions in which our studies are conducted, or the data safety monitoring board, could suspend or terminate our clinical trials or the FDA or comparable regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential drug liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Further, our current or future product candidates could cause undesirable side effects in clinical trials related to on-target toxicity. If on-target toxicity is observed, or if our current or future product candidates have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the compound.

In addition, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our current or future product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. In any such event, our studies could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The side effects experienced could affect patient recruitment or the ability of enrolled subjects to complete the study or result in potential product liability claims. Moreover, if we elect, or are required, not to initiate, or to delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly.

In addition, if our current or future product candidates receive marketing approval and we or others identify undesirable side effects caused by such current or future product candidates after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend, withdraw or limit approvals of such current or future product candidates, or seek an injunction against their manufacture or distribution;
- regulatory authorities may require the addition of labeling statements or warnings, such as a "boxed" warning or a contraindication, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such current or future product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the current or future product candidates;
- we may be required to conduct post-marketing studies or change the way the product is administered;
- regulatory authorities may require a Risk Evaluation and Mitigation Strategy ("REMS") plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such current or future product candidates from the market;
- we could be sued and held liable for injury caused to individuals exposed to or taking our current or future product candidates;
- we may be subject to fines, injunctions or imposition of criminal penalties; and
- our reputation may suffer.

These events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our current or future product candidates, if approved, and significantly impact our ability to successfully commercialize our current or future product candidates and generate revenues.

We may fail to obtain Breakthrough Therapy designation or Fast Track designation from the FDA for our current or future product candidates. Even if granted for any of our current or future product candidates, these programs may not lead to a faster development, regulatory review or approval process, and such designations do not increase the likelihood that any of our product candidates will receive marketing approval in the U.S.

We have obtained a Fast Track designation for BNC210 for the treatment of PTSD and other trauma-related and stressor-related disorders as well as for the acute treatment of anxiety in SAD patients and other anxiety-related disorders. We may also seek Fast Track designation or Breakthrough Therapy designation for one or more of our other current or future product candidates.

The sponsor of a product candidate with Fast Track designation has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the product candidate may be eligible for priority review. Such product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary

clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Product candidates designated as Breakthrough Therapies by the FDA may also be eligible for priority review and accelerated approval. Designation as a Breakthrough Therapy is within the discretion of the FDA, and in February 2025, the FDA denied our initial request for breakthrough designation. Accordingly, even if we believe one of our current or future product candidates meets the criteria for designation as a Fast Track or Breakthrough Therapy designation, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Fast Track or Breakthrough Therapy designation for a current or future product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our current or future product candidates qualify as Breakthrough Therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification and rescind the designation or decide that the time period for FDA review or approval will not be shortened.

If the market opportunities for our product candidates in SAD, PTSD, or other indications we may pursue are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability will be adversely affected, possibly materially.

The precise incidence and prevalence for the indications being pursued for our current and future product candidates is currently unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. The total addressable market opportunity for these product candidates and future product candidates will ultimately depend upon, among other things, each product candidate's proven safety and efficacy, the diagnosis criteria included in the final label for each, whether our product candidates are approved for sale for these indications, acceptance by the medical community and patient access, product pricing and reimbursement. The number of patients for our product candidates in the U.S. and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

Even if we receive marketing authorization for our product candidates, we will be subject to extensive ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If the FDA or a comparable foreign regulatory authority approves any of our current or future product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the drug will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, and continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the U.S. Any regulatory approvals that we receive for our current or future product candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the drug. Later discovery of previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance during remediation;
- revisions to the labeling, including limitation on approved uses or the addition of warnings, contraindications, or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or withdrawal of approvals;

- product seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil or criminal penalties.

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

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 current or future product candidates. We also 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. 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 may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Even if we receive marketing approval for our current or future product candidates in the United States, we may never receive regulatory approval to market our current or future product candidates outside of the United States.

We plan to seek regulatory approval of our current or future product candidates outside of the United States. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction.

For example, even if the FDA grants marketing approval of a product candidate, we may not obtain approvals in other jurisdictions, and comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among countries and can involve additional product candidate testing and administrative review periods different from those in the United States. The time required to obtain approvals in other countries might differ substantially from that required to obtain FDA approval. The marketing approval processes in other countries generally implicate all of the risks detailed above regarding FDA approval in the United States as well as other risks. In particular, in many countries outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with regulatory requirements in international markets or fail to receive applicable marketing approvals, it would reduce the size of our potential market, which could have a material adverse impact on our business, results of operations and prospects.

Changes in funding or disruptions at the FDA, the SEC, patent offices in the United States and abroad and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel, and accept the payment of user fees, and statutory, regulatory and policy changes and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency FDA have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA, patent offices in the United States and abroad and other agencies caused by funding shortages or global health concerns may also slow the time necessary for new or modified products to be developed, approved, or commercialized, which would adversely affect our business. For example, in recent years, including for 35 days beginning on December 22, 2018, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. Additionally, on

April 15, 2021, the FDA began conducting voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities in circumstances where the FDA determines that such remote evaluation would be appropriate based on mission needs and travel limitations. In July 2021, the FDA resumed standard inspectional operations of domestic facilities. Since that time, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to future pandemics, if any. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a U.S. public company, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We may in the future conduct clinical trials for current or future product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials, which may subject us to delays and expenses.

We have conducted and may in the future choose to conduct one or more of our clinical trials outside the United States, including in Australia, New Zealand, Singapore, France and the United Kingdom. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or applicable foreign regulatory authority may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless the following are true: (i) the data are applicable to the United States population and United States medical practice; (ii) the studies were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

The success of our business depends primarily on our ability to identify, develop and commercialize one or more product candidates.

We must balance our limited financial and managerial resources between BNC210 for PTSD and SAD and other product candidates and focus on clinical programs and product candidates for the indications that take advantage of our team's deep expertise and knowledge and that we believe are the most scientifically and commercially promising. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. In addition, we may spend valuable time and managerial and financial resources on clinical programs and product candidates for specific indications that ultimately do not yield any clinically or commercially viable drugs. If we do not accurately evaluate the clinical and commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in situations where it would have been more advantageous for us to retain sole rights to development and commercialization or miss out on the commercial opportunity entirely. This would adversely impact our business strategy and our financial position.

We are highly dependent on the members of our senior management and scientific staff. We may have difficulties in attracting and retaining key personnel, and if we fail to do so our business may suffer.

We are highly dependent on the members of our senior management and scientific staff, particularly our President, Chief Executive Officer and Director, Spyridon "Spyros" Papapetropoulos, M.D. and our Vice President Clinical Development, Liz Doolin, who are critical across multiple functions of our company, the loss of whose services could adversely affect the achievement of planned development objectives. We will need to hire and retain additional qualified personnel and could experience difficulty attracting and retaining such employees in the future. Competition for qualified personnel in the biotechnology and pharmaceuticals fields is intense due to the limited number of individuals who possess the skills and experience required by our industry. As such, we could have

difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

For us to further expand our drug development plans, we will need to hire additional qualified personnel. We may not be able to attract and retain personnel on acceptable terms, given the competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. Although we may be successful in attracting and retaining suitably qualified scientific and medical personnel, there can be no assurance that we will be able to attract and retain such personnel on acceptable terms given the competition for experienced scientists and clinicians from numerous pharmaceutical and chemical companies, specialized biotechnology firms, universities and other research institutions. Our failure to do so could adversely affect our business, financial condition, results of operations and prospects, and the trading price of our common stock may decline.

Our internal computer systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our drug development programs and other critical business functions.

Our internal computer systems and those of our third-party CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. In recent years, we have faced increased cybersecurity risks due to a broader reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. For example, in 2025, we became aware of a breach of our email system, which we quickly remediated and addressed. While this breach ultimately did not result in immediate material harm to us or our financial position, if such an event were to occur again, it could result in a material disruption of our programs, negatively impact our operations, financial position or prevent us from continuing our clinical trials, among other serious adverse events and impacts. Additionally, the loss of clinical trial data from completed or any future ongoing clinical trials for any of our product candidates could result in delays in our regulatory approval efforts and the loss of research data could result in delays of our research and development efforts and it would be expensive to recover or reproduce the data. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. If our third-party vendors fail to protect their information technology systems and our confidential and proprietary information, we may be vulnerable to disruptions in service and unauthorized access to our confidential or proprietary information and we could incur liability and reputational damage. 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 our product candidates could be delayed.

Risks associated with our international operations, including seeking and obtaining approval to commercialize our product candidates in foreign jurisdictions, could harm our business.

We engage extensively in international operations, which include seeking regulatory approval for certain of our product candidates in foreign jurisdictions. We expect that we are or will be subject to additional risks related to entering into these international business markets and relationships, including:

- different regulatory requirements for product and biologics approvals in foreign countries;
- differing U.S. and non-U.S. drug import and export rules;
- reduced protection for intellectual property rights in foreign countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- different reimbursement systems, and different competitive drugs and biologics;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;

•production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;

•potential liability resulting from development work conducted by distributors; and

•business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may pursue strategic transactions, such as acquisitions of companies, asset purchases, and in-licensing or out-licensing of drugs, product candidates or technologies. For example, in September 2012, we acquired Eclipse Therapeutics, Inc., a private biotechnology company. Additional potential transactions that we may consider include spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or distract our senior management or disrupt our business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

•upfront, milestone and royalty payments, equity investments and financial support of new research and development candidates including increase of personnel, all of which may be substantial;

•exposure to unknown liabilities, including potential indemnification claims from a potential spin-off or out-license of certain of our intellectual property rights;

•disruption of our business and diversion of our management's time and attention in order to develop acquired drugs, product candidates or technologies;

•incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;

•higher-than-expected acquisition and integration costs;

•lower-than-expected benefits from out-licensing or selling our technology, intellectual property or any of our subsidiaries;

•write-downs of assets or goodwill or impairment charges;

•difficulty and cost in combining or separating the operations and personnel of any acquired or sold businesses with our existing operations and personnel;

•impairment of relationships with key suppliers or customers of any acquired or sold businesses due to changes in our senior management and ownership; and

•inability to retain key employees of any acquired businesses.

Accordingly, although we cannot be certain that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks, and could harm our business, financial condition, results of operations and prospects.

Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical trials are prolonged or delayed, we, or our collaborators, may be unable to commercialize our product candidates on a timely basis.

Clinical testing of product candidates is expensive and can take a substantial period of time to complete. Clinical trial outcomes are inherently uncertain, and failure can occur at any time during the clinical development process. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials even after promising results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and initial clinical trials. Notwithstanding any potential promising results in earlier studies, we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates.

Clinical trials can be halted or delayed for a variety of reasons, including those related to:

- •side effects or adverse events in study participants presenting an unacceptable safety risk;
- •inability to reach agreements with prospective third-party CROs and clinical trial sites, or the breach of such agreements;
- •failure of third-party contractors, such as third-party CROs, or investigators to comply with regulatory requirements;
- •delay or failure in obtaining the necessary approvals from regulators, IRBs, or ethics committees to commence a clinical trial at a prospective trial site, or their suspension or termination of a clinical trial once commenced;
- •a requirement to undertake and complete additional preclinical studies to generate data required to support the submission of an NDA or a Biologics License Application ("BLA");
- •difficulty in having patients complete a trial or return for post-treatment follow-up;
- •clinical sites deviating from trial protocol or dropping out of a trial;
- •problems with Active Pharmaceutical Ingredient ("API") or drug product stability or shelf-life, storage and distribution;
- •adding new clinical trial sites;
- •our inability to manufacture, or obtain from third parties, adequate supply of API or drug product to complete our preclinical studies and clinical trials;
- •the impact of the prior COVID-19 or any future pandemic on our future clinical trials, including any enrollment delays; and
- •governmental or regulatory delays and changes in regulatory requirements, policy and guidelines.

We could also encounter delays if a clinical trial is suspended or terminated by us, by our collaborators, by the IRBs or ethics committees of the institutions in which such trial is being conducted, by any data safety monitoring board for such trial, or by the ethics committees, FDA or other regulatory authorities. Such authorities may impose a suspension or termination due to a number of factors, including: failure to conduct the clinical trial in accordance with regulatory requirements, such as the current GCPs, or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, product candidate manufacturing problems, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, delays can occur due to safety concerns arising from trials or other clinical data regarding another company's product candidate in the same compound class as one of ours.

Moreover, clinical 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 or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authorities 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 or comparable foreign regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we or our collaborators experience delays in the completion of, or termination of, any clinical trial of one of our product candidates, the commercial prospects of the product candidate will be harmed, the patent protection period during which we may have the exclusive right to commercialize our drugs could be shortened and our or our collaborators' ability to commence sales and generate revenue from the drug will be delayed. In addition, any delays in completing our clinical trials will increase our costs and slow down our product candidate development and approval process. Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Risks Related to Our Reliance on Third Parties

If our collaboration partners fail to perform as expected, fail to advance our collaboration product candidates, are unable to obtain the required regulatory approvals for our collaboration product candidates, or if the arrangements are

terminated, the potential for us to generate future revenue from such product candidates would be significantly reduced and our business would be significantly harmed.

In 2014, we entered into a research collaboration and license agreement (as amended, the "2014 Merck License Agreement") with Merck to develop compounds targeting cognitive dysfunction associated with Alzheimer's disease and other central nervous system conditions. Under the 2014 Merck License Agreement, Merck is responsible for using commercially reasonable efforts to develop, file for marketing authorization for and, following receipt thereof, to commercialize at least one product thereunder. We are dependent on Merck to provide us with any updates related to clinical trial results, serious adverse events and ongoing communications with the FDA and other regulatory agencies related to these programs, which Merck may provide or withhold in its sole discretion, and as a result we may not be able to provide material updates on a timely basis or at all with respect to these programs. In addition to our existing commercial and academic collaborations, we may also enter into collaboration agreements with other parties in the future relating to our other experimental drug candidates. Ultimately, if such drug candidates are successfully advanced through clinical trials and receive regulatory approval from the FDA, EMA or similar regulatory authorities, such collaboration partners will be responsible for commercialization of these collaboration drugs. The potential for us to obtain future development milestone payments and, ultimately, generate revenue from royalties on sales of such collaboration drugs depends entirely on successful development, regulatory approval, marketing and commercialization by our collaboration partners.

If our collaboration partners do not perform in the manner we expect or fulfil their responsibilities in a timely manner, or at all, if our agreements with them terminate or if the quality or accuracy of the clinical data they obtain is compromised, the clinical development, regulatory approval and commercialization of our collaboration product candidates could be delayed or terminated and it could become necessary, to the extent we have contractual rights to do so, for us to assume the responsibility at our own expense for these activities. In that event, we would likely be required to limit the size and scope of efforts for the development and commercialization of the affected product candidates, to seek additional financing to fund further development, or to identify alternative strategic collaboration partners, and our potential to generate future revenue from royalties and milestone payments from such product candidates would be significantly reduced or delayed and our business would be harmed. Additionally, under our current or future collaborations, our collaboration partners may not be required to disclose information regarding the status of the program, which may limit our ability to provide updates on the status of the program or input on the direction of the program.

Our existing collaborations and any future collaboration arrangements that we may enter into with third parties may not be scientifically, clinically or commercially successful. In addition to the risks inherent in the development of a product candidate, factors that may affect the success of our collaborations include the following:

- our collaboration partners have the unilateral ability to choose not to develop a collaboration drug for one or more indications for which such drug has been or is currently being evaluated, and our collaboration partners may choose to pursue an indication that is not in our strategic best interest or to forego an indication that they believe does not provide significant market potential even if clinical data are supportive of further development for such indication;

- our collaboration partners may choose not to develop and commercialize our collaboration product candidates in certain relevant markets;

- our collaboration partners may take considerably more time advancing our product candidates through the clinical and regulatory process than we currently anticipate, which could materially delay the achievement of milestones and, consequently the receipt of milestone payments from our collaboration partners;

- our collaboration partners may not inform us regarding the progress of compounds, including but not limited to whether a decision is made to advance certain compounds;

- our collaboration partners have substantial discretion under their respective agreements regarding how they structure their efforts and allocate resources to fulfil their obligations to diligently develop, manufacture, obtain regulatory approval for and commercialize our collaboration drugs;

- our collaboration partners control all aspects of commercialization efforts under their respective collaboration and license agreements and may change the focus of their development and commercialization efforts or pursue higher-priority programs and, accordingly, reduce the efforts and resources allocated to their collaborations with us;

- our collaboration partners may not pursue all indications eligible for milestones;

- our collaboration partners are solely responsible for obtaining and maintaining all regulatory approvals and may fail to develop a commercially viable formulation or manufacturing process for our product candidates, and may fail to manufacture or supply sufficient drug product for commercial use, if approved, which could result in lost revenue;

•our collaboration partners may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements;

•if any of our agreements with our collaboration partners terminate, we will no longer have any rights to receive potential revenue under such agreement, in which case we would need to identify alternative means to continue the development, manufacture and commercialization of the affected product candidates, alone or with others;

•our collaboration may have to license other patents to enable marketing of compound, and our royalties may be reduced;

•our collaboration partners have the discretion to sublicense their rights with respect to our collaboration technology in connection with collaboration product candidates to one or more third parties without our consent;

•our collaboration partners may be pursuing alternative technologies or developing alternative drugs, either on their own or in collaboration with others, that may be competitive with drugs on which they are collaborating with us or which could affect our collaboration partners' commitment to the collaboration; and

•if our collaboration partners receive approval for any of the collaboration product candidates, reductions in marketing or sales efforts or a discontinuation of marketing or sales of our product candidates by our collaboration partners would reduce any milestones and royalties we could be entitled to receive.

In addition, the 2014 Merck License Agreement (see "Business—Research Collaboration and License Agreement with Merck") and our other collaboration agreements provide Merck and our collaboration partners with rights to terminate such agreements and licenses under various conditions (including with respect to the 2014 Merck License Agreement, at Merck's convenience), which if exercised would adversely affect our drug development efforts, make it difficult for us to attract new partners and adversely affect our reputation in the business and financial communities.

The timing and amount of any milestone and royalty payments we may receive under our agreements with our collaboration partners will depend on, among other things, the efforts, allocation of resources, and successful development and commercialization of our product candidates by our collaboration partners. Any payments we may receive in connection with certain milestones or royalties under the 2014 Merck License Agreement may differ materially from those described in this Annual Report, and there can be no assurance that we will receive any such payments at all. We cannot be certain that any of the development and regulatory milestones will be achieved or that we will receive any future milestone payments under these agreements. In addition, in certain circumstances we may believe that we have achieved a particular milestone and the applicable collaboration partner may disagree with our belief. In that case, receipt of that milestone payment may be delayed or may never be received, which may require us to adjust our operating plans.

We may explore future collaborations with third parties for the development and commercialization of our current product candidates that are not partnered. If we are unable to form such collaborations or they are not successful, we may not be able to complete the development of these product candidates.

We may seek to advance the development and commercialization of our unpartnered product candidates through collaboration with third parties, including our early-stage CNS assets and oncology product candidates. If any such collaborations are established in the future, we may have limited control over the amount and timing of resources that our collaborators dedicate to the development of these product candidates. This is also likely to be true in any future collaborations with third parties once any of our product candidates are commercialized. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

We face a number of challenges in seeking future collaborations. Collaborations are complex and any potential discussions may not result in a definitive agreement for many reasons. For example, whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors, such as the design or results of our clinical trials, the potential market for our product candidates, the costs and complexities of manufacturing and delivering our product candidates to patients, the potential of competing drugs or product candidates, the existence of uncertainty with respect to ownership or the coverage of our intellectual property and industry and market conditions generally. If we determine that additional collaborations for any product candidate are necessary and are unable to enter into such collaborations on acceptable terms, we might elect to delay or scale back the development or commercialization of our product candidates in order to preserve our financial resources or to allow us adequate time to develop the required resources and systems and expertise ourselves.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. In addition, there have been a significant number of recent business combinations among large biopharmaceutical companies that have resulted in a reduced number of potential future collaborators. If a future collaborator of ours were to be involved in a business

combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

We currently rely extensively, and expect to continue to rely, on third parties to conduct and support our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing authorizations for or commercialize our current and potential future product candidates and our business could be substantially harmed.

We utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs and strategic partners to help conduct our preclinical studies and clinical trials. We rely extensively, and expect to continue to rely, on medical institutions, clinical investigators, contract laboratories, and other third parties, including collaboration partners, to conduct or otherwise support preclinical studies and clinical trials for our current and future product candidates. We continue to rely heavily on these parties for execution of preclinical studies and clinical trials for our product candidates and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs will not relieve us of our regulatory responsibilities.

We and any third parties that we contract with are required to comply with regulations and requirements, including GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area ("EEA") and comparable foreign regulatory authorities for any drugs in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or the third parties we contract with 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 perform additional clinical trials before approving our marketing applications. We cannot assure that, upon inspection, the FDA will determine that any of our current or future clinical trials will comply with GCP requirements. In addition, our clinical trials must be conducted with current or future product candidates produced under cGMP regulations and will require a large number of study subjects. Our failure or the failure of third parties that we may contract with to comply with these regulations or to recruit a sufficient number of subjects may require us to repeat some aspects of a specific, or an entire, clinical trial, which would delay the marketing approval process and could also subject us to enforcement action. We also are required to register certain then ongoing clinical trials and provide certain information, including information relating to the trial's protocol, on a government-sponsored database, such as ClinicalTrials.gov, within specific timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we have and will continue to design the preclinical studies and clinical trials for our current or future product candidates or be involved in the design when other parties sponsor the studies or trials, we anticipate that third parties will conduct all of our preclinical studies and clinical trials. As a result, many important aspects of our preclinical and clinical development are and will be outside of our direct control. Our reliance on third parties to conduct future clinical trials also results in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff, and we cannot control whether or not they will devote sufficient time and resources to our product candidates. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues; and
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If our CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, marketing approval and commercialization of our current or future product candidates may be delayed, we may not be able to obtain marketing approval and commercialize our current or future product candidates, or our development programs may be materially and irreversibly harmed. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the

size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our current or future product candidates. As a result, we believe that our financial results and the commercial prospects for our current or future product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

The third parties upon whom we rely for the supply drug product and starting materials used in our product candidates are limited in number, and the loss of any of these suppliers, or their noncompliance with regulatory requirements or our quality standards, could significantly harm our business.

The drug substance and drug product in our product candidates are supplied to us from a small number of suppliers, and in some cases sole source suppliers. Our ability to successfully develop our current or future product candidates, and to ultimately supply our commercial drugs in quantities sufficient to meet the market demand, depends in part on our ability to obtain the drug product and drug substance for these drugs in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing.

The facilities used by our contract manufacturers to manufacture our product candidates will be subject to inspections that will be conducted after we submit any marketing application to the FDA or other comparable foreign regulatory authorities. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partners for compliance with cGMP requirements and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of our product candidates. Beyond periodic audits, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve our marketing applications identifying these facilities for the manufacture of our product candidates or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require that we incur significant additional costs and materially adversely affect our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Similarly, if any third-party manufacturers on which we will rely fail to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition and prospects could be materially and adversely affected.

Further, we do not currently have arrangements in place for a redundant or second-source supply of all drug product or drug substance in the event any of our current suppliers of such drug product and drug substance cease their operations for any reason. Any delays in the delivery of our drug substance, drug product or starting materials could have an adverse effect and potentially harm our business.

For all our current or future product candidates, we intend to identify and qualify additional manufacturers to provide drug product and drug substance prior to submission of an NDA to the FDA and/or an MAA to the EMA. We are not certain, however, that our single-source and dual source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Establishing additional or replacement suppliers for the drug product and drug substance used in our current or future product candidates, if required, may not be accomplished quickly. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original supplier and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory approval, which could result in further delay. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

While we seek to maintain adequate inventory of the drug product and drug substance used in our current or future product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain drug product and drug substance from

alternate sources at acceptable prices in a timely manner, could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

We rely and will continue to rely on outsourcing arrangements for many of our activities, including clinical development and supply of BNC210.

We have a limited number of employees and, as a result, we rely on outsourcing arrangements for a significant portion of our activities, including clinical research, data collection and analysis and manufacturing. We may have limited control over these third parties, and we cannot guarantee that they will perform their obligations in an effective and timely manner.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We do not own or operate manufacturing facilities for the production of any component of BNC210, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party contract manufacturers for all of our required raw materials, drug substance and drug product for our clinical trials and to fill, label, package, store and distribute our investigational drug product. Although potential alternative suppliers and manufacturers for some components have been identified, we have not qualified these vendors to date. If we were required to change vendors, it could result in a failure to meet regulatory requirements or projected timelines and necessary quality standards for successful manufacturing of the various required lots of material for our development and commercialization efforts.

We do not have any current contractual relationships for the manufacture of commercial supplies of BNC210. If BNC210 is approved for sale by any regulatory agency, we intend to enter into agreements with third-party contract manufacturers for commercial production. The number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture bulk drug substance on a commercial scale is limited.

In addition, our reliance on third party CROs and CMOs entails further risks, including:

- non-compliance by third parties with regulatory and quality control standards;
- breach by third parties of our agreements with them;
- termination or non-renewal of an agreement with third parties; and
- sanctions imposed by regulatory authorities if compounds supplied or manufactured by a third-party supplier or manufacturer fail to comply with applicable regulatory standards.

Our success is dependent on our executive management team's ability to successfully pursue business development, strategic partnerships and investment opportunities as our company matures. We may also form or seek strategic alliances or acquisitions or enter into additional collaboration and licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances, acquisitions or licensing arrangements.

We may in the future form or seek strategic alliances or acquisitions, create joint ventures, or enter into additional collaboration and licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our current product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing shareholders or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or acquisition or other alternative arrangements for our current or future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our current or future product candidates as having the requisite potential to demonstrate safety, potency, purity and efficacy and obtain marketing approval.

Further, collaborations involving our technologies or current or future product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our current or future product candidates or may elect not to continue or renew development or commercialization of our current or future product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;

•collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

•collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our current or future product candidates

•a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;

•collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

•disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our current or future product candidates, or that result in costly litigation or arbitration that diverts management attention and resources

•collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;

•collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property; and

•collaborators may not pay milestones and royalties due to the company in a timely manner.

As a result, we may not be able to realize the benefit of our existing collaboration and licensing arrangements or any future strategic partnerships or acquisitions, collaborations or license arrangements we may enter into if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction, license, collaboration or other business development partnership, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our current or future product candidates could delay the development and commercialization of our current or future product candidates in certain geographies or for certain indications, which would harm our business prospects, financial condition and results of operations.

Manufacturing our product candidates is complex and we may encounter difficulties in production. If we encounter such difficulties, our ability to provide supply of our current or future product candidates for preclinical studies and future clinical trials or for commercial purposes could be delayed or stopped.

We do not have our own manufacturing facilities or personnel and, therefore, we currently rely, and expect to continue to rely, on third parties for the manufacture of our current or future product candidates. These third-party manufacturing providers may not be able to provide adequate resources or capacity to meet our needs and may incorporate their own proprietary processes into our product candidate manufacturing processes. We have limited control and oversight of a third party's proprietary process, and a third party may elect to modify its process without our consent or knowledge. These modifications could negatively impact our manufacturing, including product loss or failure that requires additional manufacturing runs or a change in manufacturer, either of which could significantly increase the cost of and significantly delay the manufacture of our current or future product candidates.

Manufacturing of drug products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of drug products often encounter difficulties in production, particularly in scaling up, validating the production process and assuring high reliability of the manufacturing process, including the absence of contamination. These problems include logistics and shipping, difficulties with production costs and yields, quality control, including lot consistency, stability of the product, product testing, operator error and availability of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future.

As our current or future product candidates progress through preclinical studies and clinical trials towards potential approval and commercialization, it is expected that various aspects of the manufacturing process will be altered in an effort to optimize processes and results. Such changes may require amendments to be made to regulatory applications which may further delay the timeframes under which modified manufacturing processes can be used for any of our current or future product candidates and additional bridging studies or trials may be required and may not be successful. We may be unsuccessful in demonstrating the comparability of clinical

supplies which could require the conduct of additional clinical trials. Any such delay could have a material adverse impact on our business, results of operations and prospects.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about us and the diseases our products are designed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear and create uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to comment on the effectiveness of a product or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend ourselves or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. Further, there is a risk that unmerited or unsupported claims about our products may circulate on social media. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face overly restrictive regulatory actions, or incur other harm to us and our business, including damage to the reputation of our products, as well as the negative impact on the value of our assets and securities.

Risks Related to Commercialization of our Product Candidates

Even if we receive marketing approval for our current or future product candidates, our current or future product candidates may not achieve broad market acceptance, which would limit the revenue that we generate from their sales.

The commercial success of our current or future product candidates, if approved by the FDA or other applicable regulatory authorities, will depend upon the awareness and acceptance of our current or future product candidates among the medical community, including physicians, patients and healthcare payors. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. Market acceptance of our current or future product candidates, if approved, will depend on a number of factors, including, among others:

- the efficacy of our current or future product candidates as demonstrated in clinical trials, and, if required by any applicable regulatory authority in connection with the approval for the applicable indications, to provide patients with incremental health benefits, as compared with other available medicines;
- the timing of market introduction of the product candidates and potential advantages to alternative treatments;
- limitations or warnings contained in the labeling approved for our current or future product candidates by the FDA or other applicable regulatory authorities;
- the clinical indications for which our current or future product candidates are approved;
- availability of alternative treatments already approved or expected to be commercially launched in the near future;
- the potential and perceived advantages of our current or future product candidates over current treatment options or alternative treatments, including future alternative treatments;
- the willingness of the target patient population to try new therapies or treatment methods and of physicians to prescribe these therapies or methods;
- the need to dose such product candidates in combination with other therapeutic agents, and related costs;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- our ability to obtain and maintain intellectual property protection;

- pricing and cost effectiveness;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness of our current or future product candidates;
- our ability to obtain sufficient third-party coverage or reimbursement; or
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If our current or future product candidates are approved but do not achieve an adequate level of acceptance by patients, physicians and payors, we may not generate sufficient revenue from our current or future product candidates to become or remain profitable. Before granting reimbursement approval, healthcare payors may require us to demonstrate that our current or future product candidates, in addition to treating these target indications, also provide incremental health benefits to patients. Our efforts to educate the medical community, patient organizations and third-party payors about the benefits of our current or future product candidates may require significant resources and may never be successful.

If we are unable to establish sales, marketing and distribution capabilities for any product candidate that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have sales, marketing or distribution infrastructure. To achieve commercial success for any product candidate for which we may obtain marketing approval, we will need to establish a sales, marketing and distribution organization. In the future, we expect to build a focused sales and marketing infrastructure to market some of our product candidates in the United States, if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to market our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, once approved;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales, marketing and distribution capabilities and are forced to enter into arrangements with, and rely on, third parties to perform these services, our revenue and our profitability, if any, are likely to be lower than if we had developed such capabilities ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively.

There can be no assurance that we will be able to develop in-house sales, marketing and distribution capabilities or establish or maintain relationships with third parties to commercialize any product in the United States or overseas. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we do.

The development and commercialization of new drugs is highly competitive. We face and will continue to face competition from third parties that use drug technologies similar to ours and from companies focused on more traditional therapeutic modalities. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct

research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization of new drugs.

There are currently no FDA-approved drugs for the acute treatment of SAD. There are three FDA-approved generic antidepressants for treatment of SAD that include paroxetine (Paxil), sertraline (Zoloft) and venlafaxine (Effexor). Although not FDA-approved for the acute treatment of SAD, generic benzodiazepines and beta blockers are used off-label as well. Additionally, we are aware of several product candidates in clinical development that are being developed for the acute treatment of SAD, by VistaGen Therapeutics, among others.

There are two FDA-approved generic antidepressants indicated to treat PTSD, sertraline (Zoloft) and paroxetine (Paxil). In addition, the most recent and relevant PTSD treatment guidelines from the American Psychological Association and the U.S. Department of Veteran Affairs and Department of Defense published in 2017 also recommend fluoxetine (Prozac) or venlafaxine (Effexor). We are aware of several other companies seeking to find improved therapeutics for PTSD by exploring mechanisms of action different from the approved SSRIs, including Lykos Therapeutics, among others.

Many of our current or future competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and reimbursement and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific, sales, marketing and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we or our collaborators may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our current or future product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Third-party payor coverage and reimbursement status of newly-approved drugs is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those drugs and decrease our ability to generate revenue.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all, or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford drugs such as our product candidates, assuming approval. Our ability to achieve acceptable levels of coverage and reimbursement for drugs by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize and attract additional collaboration partners to invest in the development of our product candidates. We cannot provide any assurance that coverage and reimbursement in the United States, the European Union or elsewhere will be available for any drug that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future. Third-party payors increasingly are challenging prices charged for pharmaceutical products and services. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on drugs that we may develop.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved drugs. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;

- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price ("ASP") and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical drugs are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical drugs, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our drugs may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved drugs and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new drugs.

We are exposed to potential product liability or similar claims, and insurance against these claims may not be available to us at a reasonable rate in the future or at all.

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing and marketing of human therapeutic drugs. Clinical trials involve the testing of product candidates on human subjects or volunteers under a research plan and carry a risk of liability for personal injury or death to patients due to unforeseen adverse side effects, improper administration of the product candidate or other factors. Many of these patients are already seriously ill and are therefore particularly vulnerable to further illness or death.

We currently carry clinical trial liability insurance in the amount of $10.0 million in the aggregate, but there can be no assurance that we will be able to maintain such insurance or that the amount of such insurance will be adequate to cover claims. We could be materially and adversely affected if we were required to pay damages or incur defense costs in connection with a claim outside the scope of indemnity or insurance coverage, if the indemnity is not performed or enforced in accordance with its terms or if our liability exceeds the amount of applicable insurance. In addition, there can be no assurance that insurance will continue to be available on terms acceptable to us, if at all, or that if obtained, the insurance coverage will be sufficient to cover any potential claims or liabilities. Similar risks would exist upon the commercialization or marketing of any drugs by us or our collaborators.

Regardless of their merit or eventual outcome, product liability claims may result in:

- decreased demand for any of our future drugs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;

- costs of litigation;
- distraction of management; and
- substantial monetary awards to plaintiffs.

Should any of these events occur, they could have a material adverse effect on our business, results of operations and financial condition that could adversely affect the trading price of our ADSs.

Risks Related to Regulation of Our Industry

The regulatory approval processes of the FDA, EMA and comparable authorities are lengthy, time consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug and biologic products are subject to extensive regulation by the FDA, EMA and comparable regulatory authorities in other jurisdictions, which regulations differ from country to country. Neither we nor any of our collaboration partners is permitted to market any drug or biologic products in the United States until we receive regulatory approval from the FDA. Equally, neither we nor any of our collaboration partners is permitted to market any drug or biologic in the EEA, until we receive a marketing authorization from the EMA or EEA Member State Competent Authorities. We have not submitted an application or obtained regulatory approval for any of our product candidates anywhere in the world. Obtaining regulatory approval of an NDA, BLA or marketing authorization, can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable U.S., EEA and other comparable regulatory requirements may subject us to administrative or judicially imposed sanctions or other actions, including:

- untitled or warning letters;
- civil and criminal penalties;
- injunctions;
- withdrawal of regulatory approval of drugs;
- drug seizure or detention;
- drug recalls;
- total or partial suspension of production; and
- refusal to approve pending NDAs, BLAs, marketing authorization applications, or supplements to approved NDAs, BLAs or extensions or variations to marketing authorizations.

Prior to obtaining approval to commercialize a product candidate in the United States, the EEA, or elsewhere, we or our collaboration partners must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, EMA or other similar regulatory authorities, that such product candidates are safe and effective for their intended uses. The number of preclinical studies and clinical trials that will be required for approval by the FDA, EMA or other regulatory authorities varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA, EMA and other regulatory authorities. Administering product candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials and result in the FDA, EMA or other regulatory authorities denying approval of a product candidate for any or all targeted indications.

The time required to obtain approval by the FDA, EMA and comparable authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors. The FDA, EMA and comparable authorities have substantial discretion in the approval process and we may encounter matters with the FDA, EMA or such comparable authorities that requires us to expend additional time and resources and delay or prevent the approval of our product candidates. For example, the FDA or EMA may require us to conduct additional studies or trials for product candidates either prior to or post-approval, such as additional drug-drug interaction studies or safety or efficacy studies or trials, or it may object to elements of our clinical development program such as the number of subjects in our current clinical trials from the United States. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical

development and may vary among jurisdictions, which may cause delays in the approval or result in a decision not to approve an application for regulatory approval. Despite the time and expense exerted, failure can occur at any stage. Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA, EMA or other comparable regulatory authorities may disagree with the design or implementation of our, or our collaboration partners', clinical trials;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which approval is sought;
- the FDA, EMA or comparable regulatory authorities may disagree with the interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA, a BLA, marketing authorization application, or other submission or to obtain regulatory approval in the United States, the EEA, Australia or elsewhere;
- we, or our collaboration partners, may be unable to demonstrate to the FDA, EMA or comparable regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or comparable regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers responsible for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failure to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, financial condition, results of operations and prospects. Additionally, if the FDA, EMA or other regulatory authority requires that we conduct additional clinical trials, places limitations on our label, delays approval to market our product candidates or limits the use of our drugs, our business and results of operations may be harmed.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our drugs, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of any future drug. Any of the foregoing scenarios could harm the commercial prospects for our drugs.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which could prevent or delay regulatory approval and commercialization.

We have not completed all the clinical trials necessary to support an application with the FDA, EMA or other regulatory authority for approval to market any of our product candidates. Before obtaining regulatory approvals for the commercial sale of our drugs, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that the product candidate is both safe and effective for use in each target indication. Clinical trials often fail to demonstrate safety and efficacy of the product candidate studied for the target indication. Most product candidates that commence clinical trials are never approved as drugs. If our product candidates are not shown to be both safe and effective in clinical trials, we will not be able to obtain regulatory approval or commercialize these product candidates. In such case, we would need to develop other compounds and conducting associated preclinical studies and clinical trials, as well as the potential need for additional financing, would have a material adverse effect on our business, financial condition, results of operations and prospects.

The results of any Phase 3 or other pivotal clinical trial may not be adequate to support marketing approval. These clinical trials are lengthy and, with respect to non-orphan indications, usually involve many hundreds to thousands of patients. In addition, if the FDA, EMA or another applicable regulator disagrees with our or our collaborator's choice of the key testing criteria or primary endpoint, or the results for the primary endpoint are not robust or significant relative to the control group of patients not receiving the experimental therapy, such regulator may refuse to approve our product candidate in the region in which it has jurisdiction. The FDA, EMA or other applicable regulators also may require additional clinical trials as a condition for approving any of these product candidates.

Changes in methods of product candidate manufacturing, formulation and mixed clinical trial results calling for an altered clinical approach may result in additional costs or delay.

As product candidates are developed through preclinical to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates or jeopardize our or our collaborators' ability to commence drug sales and generate revenue. For example, following our Phase 2 RESTORE clinical trial in patients diagnosed with PTSD, which did not meet its primary endpoint, we reformulated BNC210 to be in tablet form to address limitations of the liquid suspension formulation used in the RESTORE trial, including overcoming the food effect (i.e. the requirement to be given with food), improving patient compliance and providing rapid absorption, dose linear pharmacokinetics and ability to reach blood exposure predicted from the pharmacometrics analysis as necessary to give us a higher probability of success in a subsequent PTSD trial. This resulted in additional costs and delays in our clinical program such as the need to conduct trials to demonstrate the clinical safety and pharmacokinetic activity of the tablet formulation and delays in the reporting of topline results in PTSD that may cause delays in initiation of Phase 3 registrational studies in the indication. Similarly, our Phase 2 PREVAIL trial for BNC210 for the acute treatment of SAD did not meet its primary endpoint. We then conducted a post-hoc in-depth analysis of the full dataset to better understand the true potential of the drug and guide late-stage trial design. These items have resulted in additional costs and delays in our clinical program such as the need to conduct trials to demonstrate the clinical safety, pharmacokinetic activity and stability of the tablet formulation and delays in the reporting of topline results in PTSD that may cause delays in initiation of Phase 3 registrational studies in the indication. There can be no assurance we will not have to alter manufacturing methods or formulations in the future and we will be able to recruit future trials based on projected timelines. These may result in additional costs or delays and materially adverse our business.

Even if we obtain and maintain approval for our product candidates from one jurisdiction, we may never obtain approval for our product candidates in other jurisdictions, which would limit our market opportunities and adversely affect our business.

Sales of our approved drugs will be subject to U.S. and non-U.S. regulatory requirements governing clinical trials and regulatory approval, and we plan to seek regulatory approval to commercialize our product candidates in the United States, the EEA, and other countries. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. For example, approval in the United States by the FDA does not ensure approval by the regulatory authorities in other countries or jurisdictions, and similarly approval by a non-U.S. regulatory authority, such as the EMA, does not ensure approval by regulatory authorities in other countries, including by the FDA. However, the failure to obtain approval in one jurisdiction may have a negative impact on our ability to obtain approval elsewhere. Approval processes and regulatory requirements vary among countries and can involve additional drug testing and validation and additional administrative review periods. Even if a drug is approved, the FDA or EMA, as the case may be, may limit the indications for which the drug may be marketed, require extensive warnings on the drug labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for a drug is also subject to approval. Regulatory authorities in other countries also have their own requirements for approval of product candidates with which we must comply prior to marketing in those countries. Obtaining non-U.S. regulatory approvals and compliance with such non-U.S. regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our current and any future drugs, in certain countries. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our product candidates will be unrealized.

We may be subject to healthcare laws, regulation and enforcement and our failure to comply with these laws could harm our results of operations and financial conditions.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The U.S. Department of Health and Human Services ("HHS"), Office of Inspector General ("OIG"), heavily scrutinizes relationships

between pharmaceutical companies and persons in a position to generate referrals for or the purchase of their products, such as physicians, other healthcare providers, and pharmacy benefit managers, among others;

•the federal civil monetary penalty laws and civil and criminal false claims laws and, such as the federal False Claims Act, which imposes criminal and civil penalties, including through civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. Federal Government, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. Federal Government. In addition, the Government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false of fraudulent claim for purposes of the False Claims Act. Manufacturers can be held liable under the False Claims Act, even when they do not submit claims directly to government payors, if they are deemed to have "caused" the submission of the claim. The False Claims Act allows private individuals acting as "whistleblowers" to bring actions on the U.S. Federal Government's behalf and to share in any recovery;

•the U.S. federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or 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; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

•the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services information related to certain payments and other transfers of value to physicians (as defined by statute), certain non-physician practitioners (including nurse practitioners, certified nurse anesthetists, physician assistants, clinical nurse specialists, anesthesiology assistants and certified nurse midwives) as well as teaching hospitals. Manufacturers are also required to disclose ownership and investment interests held by physicians and their immediate family members;

•federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and

•federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers.

We are also subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. There are ambiguities as to what is required to comply with these state requirements, and if we fail to comply with an applicable state law requirement, we could be subject to penalties.

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, the exclusion from participation in federal and state government funded healthcare programs, such as Medicare and Medicaid, reputational harm, and the curtailment or restructuring of our operations. It may also subject us to additional reporting obligations and oversight, if we become subject to a corporate integrity agreement, deferred prosecution agreement, or other agreement to resolve allegations of non-compliance with these laws. If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to similar criminal, civil or

administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

Our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners may engage in fraudulent conduct or other illegal activities. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate: (i) the regulations of the FDA, EMA and other regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad; or (iv) laws that require the reporting of true, complete and accurate financial information and data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, 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 could also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent misconduct 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 comply 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 and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of federal and state initiatives in the United States that seek to reduce healthcare costs. For example, in 2010, the Affordable Care Act ("ACA") was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the biotechnology and pharmaceutical industries are the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;

- 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;

- extension of a manufacturer's Medicaid rebate obligation to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

•a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and

•establishment of the Center for Medicare and Medicaid Innovation at the Centers for Medicare & Medicaid Services (“CMS”) to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, Congressional and executive challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court’s decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures, if any, will impact our business.

In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted.

•On August 2, 2011, the U.S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022. Under current legislation, the actual reduction in Medicare payments varies from 1% from April 1, 2022, through June 30, 2022, to up to 3% in the final fiscal year of this sequester, unless additional Congressional action is taken.

•On January 2, 2013, the U.S. American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers.

•On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

•On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

•On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.

•On August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law, which, among other things, requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (began in 2023), and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025).

•On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was signed into law, which is expected to have significant effects on biotech companies, including tax incentives that benefit biotech innovation. The OBBBA also restores the ability for companies to immediately deduct domestic research and experimentation (R&E) costs, a provision that was previously phased out. This change provides significant tax relief and increases cash flow for biotech and life sciences companies, especially small and early-stage companies. Additionally, OBBBA amends the Inflation Reduction Act to be more favorable for orphan drug developers by allowing a drug with multiple orphan designations to remain exempt from price negotiation, potentially preserving profitability for rare disease therapies.

•The OBBBA also mandates that able-bodied Medicaid recipients aged 19-64 must work, volunteer, or attend school for at least 80 hours per month, or risk losing coverage. This is expected to reduce costs, but potentially also coverage for millions of people.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the way manufacturers set prices for their marketed products, which has already resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. Federal Government will pay for healthcare drugs and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. 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. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

In the EEA, similar political, economic and regulatory developments may affect our ability to profitably commercialize our current or any future drugs. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EEA or member state level may result in significant additional requirements or obstacles that may increase our operating costs. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific drugs and therapies.

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. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal data, such as information that we may collect in connection with clinical trials in the United States and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In Australia, Australia's Privacy Act 1988 imposes mandatory data breach notification requirements providing that where personal information is lost or is subject to unauthorized access or disclosure, and that would be likely to lead to serious harm, then affected individuals and the Information Commissioner must be notified within 30 days. A failure to notify can result in penalties of up to A$2.2 million. Further, the sending of commercial electronic messages without prior consent is prohibited under Australia's Spam Act 2003. Violations of this legislation are subject to penalties of up to A$2.1 million for repeat offenders, and the regulator, the Australian Communications and Media Authority, is active in monitoring market behavior and prosecuting infringements. Obligations and restrictions imposed by current and future applicable laws, regulations, contracts, and industry standards may affect our ability to provide all the current features of our products and subscriptions and our customers' ability to use our products and subscriptions and could require us to modify the features and functionality of our products and subscriptions.

In the United States, HIPAA imposes certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In addition, the California Consumer Privacy Act ("CCPA") went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. Further, the California Privacy Rights Act ("CPRA") recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

In Europe, the European General Data Protection Regulation ("GDPR") went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. Further, following the withdrawal of the United Kingdom from the EU on January 31, 2020, and since the expiration of the transition period on January 1, 2021, companies have had to comply with the GDPR and also the United Kingdom GDPR (the "UK GDPR") which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient patent and other intellectual property protection for our product candidates and technology, our competitors could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our market or successfully commercialize any product candidates we may develop.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market. Our success depends in large part on our ability to obtain and maintain patent protection for our platform technologies, product candidates and their uses, as well as our ability to operate without infringing the proprietary rights of others. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. Our pending and future patent applications may not result in patents being issued or that issued patents will afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or product candidates.

Composition of matter patents for biological and pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications directed to composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office ("USPTO") or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. The

patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent position of pharmaceutical and biotechnology companies generally is highly uncertain and involves complex legal and factual questions for which many legal principles remain unresolved. Our pending and future patent applications may not result in patents being issued in the United States or in other jurisdictions which protect our technology or products, or which effectively prevent others from commercializing competitive technologies and products. There is no assurance that all the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. For example, our pending patent applications may be subject to third-party pre-issuance submissions of prior art to the USPTO or our issued patents may be subject to post-grant review proceedings, oppositions, derivations, reexaminations, or inter partes review proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technologies and products, or limit the duration of the patent protection of our technologies and products. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. If the breadth or strength of the claims of our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize our current product candidates or future product candidates, or could have a material adverse effect on our ability to raise funds necessary to continue our research programs or clinical trials.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other countries. Competitors may use our technologies in countries where we have not obtained patent protection to develop their own products and further, may infringe our patents in territories where we have patent protection, but enforcement is not as strong as in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements.

Periodic maintenance fees, renewal fees, annuities fees and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application.

The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured

by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours for a meaningful amount of time, or at all.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union and certain other countries. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be expected, and our competitive position, business, financial condition, results of operations and prospects could be materially adversely affected.

Changes in U.S. patent laws, or laws in other countries, could diminish the value of patents in general and may limit our ability to obtain, defend, and/or enforce our patents.

Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Further, because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii)

invent any of the inventions claimed in our or our licensor's patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

Some of our intellectual property is licensed to us by a third party. If we fail to comply with our obligations in the agreement under which we license intellectual property rights from that third party, or otherwise experience disruptions to our business relationships with our licensor, we could lose license rights that are important to our business.

We are party to license agreements that enable us to utilize third-party proprietary technologies in the development of our product candidates, and we may in the future enter into more license agreements with third parties under which we receive rights to intellectual property that are important to our business. These intellectual property license agreements may require us various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements (including as a result of COVID-19 impacting our operations), we use the licensed intellectual property in an unauthorized manner or we are subject to bankruptcy-related proceedings, the terms of the licenses may be materially modified, such as by rendering currently exclusive licenses non-exclusive, or it may give our licensors the right to terminate their respective agreement with us, which could limit our ability to implement our current business plan and materially adversely affect our business, financial condition, results of operations and prospects.

We may also in the future enter into license agreements with third parties under which we are a sublicensee. If our sublicensor fails to comply with its obligations under its upstream license agreement with its licensor, the licensor may have the right to terminate the upstream license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on reasonable terms, or at all, which may impact our ability to continue to develop and commercialize our product candidates incorporating the relevant intellectual property.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and/or defense of patents and patent applications that are licensed to us. Consequently, our success will depend, in part, on the ability of our licensors to obtain, maintain and enforce patent protection for our licensed intellectual property, in particular, those patents to which we have secured exclusive rights, and any such licensed patents and patent applications may not be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. For instance, we cannot be certain that such activities by licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. Further, it is possible that the licensors' infringement proceeding, or defense activities may be less vigorous than had we conducted them ourselves. If our current or future licensors, licensees or collaborators fail to prepare, file, prosecute, maintain, enforce, and defend licensed patents and other intellectual property rights, such rights may be reduced or eliminated, and our right to develop and commercialize our product candidates or technology that is the subject of such licensed rights could be adversely affected. In addition, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights.

Licensing of intellectual property is important to our business and involves complex legal, business and scientific issues and certain provisions in intellectual property license agreements may be susceptible to multiple interpretations. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;

•our right to sublicense patents and other rights to third parties;

•our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;

•our right to transfer or assign the license; and

•the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could harm our business, financial condition, results of operations and prospects. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms or at all, we may be unable to successfully develop and commercialize our product candidates. Moreover, any dispute or disagreement with our licensing partners may result in the delay or termination of the research, development or commercialization of our product candidates or any future product candidates and may result in costly litigation or arbitration that diverts management attention and resources away from our day-to-day activities, which may adversely affect our business, financial conditions, results of operations and prospects.

In addition, certain of our future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, we may in the future enter into license agreements that are not assignable or transferable, or that require the licensor's express consent for an assignment or transfer to take place.

Our intellectual property licensed from third parties may be subject to retained rights.

Our current and future licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (the "Bayh-Dole Act"). The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

If we are unable to obtain intellectual property licenses from third parties on commercially reasonable terms or at all, our business could be harmed.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. The licensing of third-party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. More established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize our product candidates, which could materially harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be or become non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

Any issued patents we may own covering our product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the USPTO.

Any of our intellectual property rights could be challenged or invalidated despite measures we take to obtain patent and other intellectual property protection with respect to our product candidates and proprietary technology. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States and in some other jurisdictions, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO or the applicable foreign counterpart, or made a misleading statement, during prosecution. A litigant or the USPTO itself could challenge our patents on this basis even if we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith. The outcome following such a challenge is unpredictable.

With respect to challenges to the validity of our patents, there might be invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. The cost of defending such a challenge, particularly in a foreign jurisdiction, and any resulting loss of patent protection could have a material adverse impact on one or more of our product candidates and our business. Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend, particularly in a foreign jurisdiction, and could require us to pay substantial damages, cease the sale of certain products or enter into a license agreement and pay royalties, which may not be possible on commercially reasonable terms or at all. Any efforts to enforce our intellectual property rights are also likely to be costly and may divert the efforts of our scientific and management personnel.

Litigation or other proceedings or third-party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from developing or selling our products.

Our commercial success will depend in part on not infringing the patents or violating the other proprietary rights of others. Significant litigation regarding patent rights occurs in our industry. Because the intellectual property landscape in the pharmaceutical and biotechnology industry is rapidly evolving and interdisciplinary, it is difficult to conclusively assess our freedom to operate without infringing on third party rights. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. We do not always conduct independent reviews of patents issued to third parties. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived, so there may be applications of others now pending or recently revived patents of which we are unaware. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. Third parties may, in the future, assert claims that we are employing their proprietary technology without authorization, including claims from competitors or from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. As we continue to commercialize our products in their current or updated forms, launch new products and enter new markets, we expect competitors may claim that one or more of our products infringe their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technology involved, and the uncertainty of litigation may increase the risk of business resources and management's attention being diverted to patent litigation. We have, and we may in the future, receive letters or other threats or claims from third parties inviting us to take licenses under, or alleging that we infringe, their patents.

Moreover, we may become party to future adversarial proceedings regarding our patent portfolio or the patents of third parties. Such proceedings could include supplemental examination or contested post-grant proceedings such as review, reexamination, inter parties review, interference or derivation proceedings before the USPTO and challenges in U.S. District Court. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Also, our patents may be subjected to opposition, post-grant review or comparable proceedings lodged in various foreign, both national and regional, patent offices.

The legal threshold for initiating litigation or contested proceedings may be low, so that even lawsuits or proceedings with a low probability of success might be initiated. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. We may also occasionally use these proceedings to challenge the patent rights of others. We cannot be certain that any particular challenge will be successful in limiting or eliminating the challenged patent rights of the third party.

Any lawsuits resulting from such allegations could subject us to significant liability for damages and invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing;
- pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;
- redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and infeasible; and
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all, or from third parties who may attempt to license rights that they do not have.

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation.

If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages, which may be increased up to three times of awarded damages, and/or substantial royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. We could encounter delays in product introductions while we attempt to develop alternative methods or products. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products.

Further, competitors or third parties may infringe or otherwise violate our intellectual property. To counter infringement or other violations, we may be required to file claims, which can be expensive and time consuming. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In such a case, we could ultimately be forced to cease use of such marks. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be commercially valuable. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications or those of our future licensors is threatened, it could dissuade other companies from collaborating with us to license, develop or commercialize current or future product candidates. Such a loss of patent protection would have a material adverse impact on our business.

Also, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

In addition, if our current or future product candidates are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our licensees and other parties with whom we have business relationships, and we may be required to indemnify those parties for any damages they suffer as a result of these claims. Such claims may require us to initiate or defend protracted and costly litigation on behalf of licensees and other parties regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third-party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our shareholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technologies or other product candidates, or enter into development partnerships that would help us bring our product candidates to market.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

We also rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Elements of our product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Trade secrets and know-how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and non-disclosure obligations. We further seek to protect our potential trade secrets, proprietary know-how, and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. We cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position would be harmed.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information or alleged trade secrets of third parties or competitors or are in breach of non-competition or non-solicitation agreements with our competitors or their former employers.

As is common in the biotechnology and pharmaceutical industries, we employ individuals and engage the services of consultants who previously worked for other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that our consultants have used or disclosed trade secrets or other proprietary information of their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, opposed, infringed, circumvented, invalidated, cancelled, declared generic, determined to be not entitled to registration, or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Any trademark litigation could be expensive. In addition, we could be found liable for significant monetary damages, including treble damages, disgorgement of profits and attorneys' fees, if we are found to have willfully infringed a trademark. We may not be able to protect our exclusive right to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential collaborators or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk management and strategy

Neuphoria recognizes the critical importance of developing, implementing, and maintaining robust cybersecurity measures to safeguard our information systems and protect the confidentiality, integrity and availability of our data.

Managing Material Risks & Integrated Overall Risk Management

Our risk management team has evaluated and addressed cybersecurity risks in alignment with our business objectives and operational needs and have integrated them into our overall risk management system.

Engage Third-parties on Risk Management

Recognizing the complexity and evolving nature of cybersecurity threats, Neuphoria has and engaged with a range of external experts, including cybersecurity assessors, consultants, advisors, and auditors in evaluating and testing our risk management systems. These partnerships will enable us to leverage specialized knowledge and insights, ensuring our cybersecurity strategies and processes remain at the forefront of industry best practices.

Oversee Third-party Risk

Because we are aware of the risks associated with third-party service providers, Neuphoria will implement stringent processes to oversee and manage these risks. We will conduct thorough security assessments of all third-party providers before engagement and maintain ongoing monitoring to ensure compliance with our cybersecurity standards.

Risks from Cybersecurity Threats

While we have encountered cybersecurity threats, including a breach of an administrative email account, these challenges have not resulted in the loss of any data, materials, or clinical information, and have not materially impaired our operations or financial standing.

Governance

Board of Directors Oversight

The Audit & Risk Management Committee is central to the Board's oversight of cybersecurity risks and bears the primary responsibility for this domain. The Audit & Risk Management Committee is composed of board members with diverse expertise including risk management, technology, and finance, equipping them to oversee cybersecurity risks effectively.

Risk Management Personnel

Our IT Manager is actively involved in assessing, monitoring and managing our cybersecurity risks. He has over 30 years of experience in the field of cybersecurity, and his in-depth knowledge and experience are instrumental in developing and executing our cybersecurity strategies.

Monitor Cybersecurity Incidents

Our IT Manager implements and oversees processes for the regular monitoring of our information systems, which includes having a well-defined incident response plan. In the event of a cybersecurity incident, we can take immediate actions to mitigate the impact and long-term strategies for remediation and prevention of future incidents.

Reporting to Management and the Board of Directors

Our IT Manager will provide regular updates to our CEO, Spyros Papapetropoulos, regarding all aspects related to cybersecurity risks and incidents. This ensures that the highest levels of management are kept abreast of the cybersecurity posture and potential risks faced by Neuphoria. Furthermore, significant cybersecurity matters and strategic risk management decisions are escalated to the Board of Directors, ensuring that they have comprehensive oversight and can provide guidance on critical cybersecurity issues.

Item 2. Properties

We have offices located at 200 Greenhill Road, Eastwood, South Australia 5063, Australia, where we lease approximately 435 square meters of office space. The lease for our current headquarters expires on May 31, 2026, if not sooner terminated. We believe that our existing facilities are adequate for our near-term needs. We believe that suitable additional or alternative space would be available if required in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

Our management is not aware of any current formal claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations, financial condition or cash flows. From time to time, we may become involved in legal proceedings relating to claims arising from the ordinary course of business. We intend to defend vigorously against any future claims and litigation.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Our ADSs commenced trading on the Nasdaq Global Market on December 17, 2021 under the symbol "BNOX" and continued to do so until December 23, 2024, the date prior to the effectiveness of our redomiciliation as a U.S. domestic company. Beginning on December 24, 2024, Neuphoria's shares of common stock began trading on the Nasdaq Global Market under the trading symbol "NEUP". Prior to this, no public market existed in the United States for our ADSs or other securities. Prior to delisting from the ASX in August 2023, our ordinary shares were publicly traded on the Australian Securities Exchange under the symbol "BNO".

As of June 30, 2025, there were 3,122 holders on record of our ordinary shares. This number is not representative of the number of beneficial holders of our shares or common stock nor are they representative of where such beneficial holders reside, as many of these ordinary shares and common stock were held of record by brokers or other nominees.

Dividends

We have not paid cash dividends on our shares of common stock, or previously on ordinary shares or ADSs, to date, and we intend to retain all available funds and any future earnings for use in the operation of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any future determination to declare cash dividends will be made at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

In the fiscal year ended June 30, 2025, we did not declare or pay any dividends.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

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

The following discussion and analysis of the Company's financial condition and results of operations should be read in conjunction with our audited financial statements and the notes related thereto which are included in "Item 8. Financial Statements and Supplementary Data" of this Annual Report on Form 10-K. Certain information contained in the discussion and analysis set forth below includes forward-looking statements. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those set forth under "Special Note Regarding Forward-Looking Statements," "Item 1A. Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Overview

We are a clinical-stage biopharmaceutical company developing novel, allosteric ion channel modulators designed to transform the lives of patients suffering from serious central nervous system ("CNS") disorders with high unmet medical need. Ion channels serve as important mediators of physiological function in the CNS and the modulation of ion channels influences neurotransmission that leads to downstream signaling in the brain. The α7 nicotinic acetylcholine ("ACh") receptor ("α7 receptor") is an ion channel that plays an important role in driving emotional responses and cognitive performance. Utilizing our expertise in ion channel biology and translational medicine, we are developing orally active small molecule negative allosteric modulators ("NAMs") to treat anxiety and stressor-related disorders. In addition, through a long-standing strategic partnership with Merck & Co., Inc., in the United States and Canada ("Merck"), we are also developing positive allosteric modulators ("PAMs") of the α7 receptor to treat cognitive dysfunction. Neuphoria's pipeline also includes preclinical assets that target Kv3.1/3.2 ion channels being developed for CNS conditions of high unmet need.

We are advancing our lead product candidate, BNC210, an oral, proprietary, selective NAM of the α7 receptor, for the the acute treatment of Social Anxiety Disorder ("SAD") and chronic treatment of Post-Traumatic Stress Disorder ("PTSD"). There remains a significant unmet medical need for the over 27 million patients in the United States alone suffering from SAD and PTSD.

Current pharmacological treatments include certain antidepressants and benzodiazepines, and there have been no new FDA approved therapies in these indications in nearly two decades. These existing treatments have multiple shortcomings, such as a slow onset of action of antidepressants, and significant side effects of both classes of drugs, including abuse liability, addiction potential and withdrawal symptoms. BNC210 has been observed in our clinical trials to have a fast onset of action and clinical activity without the limiting side effects seen with the current standard of care.

We were incorporated in 1996, completed our initial public offering and listing of ordinary shares on the ASX in 1999 and completed our initial public offering and listing of our ADSs on the Nasdaq in 2021. On July 25, 2023, we requested to be delisted from the official list of the ASX, which became effective August 28, 2023 and, as a result, our ordinary shares are no longer quoted or traded on the ASX.

Our ability to generate revenue from product sales sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. As of June 30, 2025, our operations have been financed primarily by aggregate net proceeds of $193.0 million from the sale and issuances of our equity, $29.2 million in the form of upfront payments, research funding, and a milestone payment from the 2014 Merck License Agreement, and $67.1 million from Australian research and development credits and government grants and assistance.

Since inception, we have had significant operating losses. Our net loss after tax was $0.4 million and $15.5 million for the twelve months ended June 30, 2025 and 2024, respectively. As of June 30, 2025, we had an accumulated deficit of $178.3 million and cash and cash equivalents of $14.2 million.

Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our accounts payable and accrued expenses. We expect to continue to incur net losses for the foreseeable future, and we expect our research and development expenses, and our administrative and other expenses will continue to increase. In particular, we expect our expenses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, as well as hire additional personnel, pay fees to outside consultants, lawyers and accountants, and incur other increased costs associated with being a U.S. public company, hiring U.S. personnel and establishing a U.S. infrastructure. In addition, if we seek and obtain regulatory approval to commercialize any product candidate, we will also incur increased expenses in connection with commercialization and marketing of any such product. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditure on other research and development activities.

In accordance with ASC 205-40, *Going Concern*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date these consolidated financial statements are issued. The Company incurred a net loss of $0.4 million for the twelve months ended June 30, 2025 inclusive of the receipt of milestone payments associated with our research collaboration and licensing agreements and

incurred a net loss of $15.5 million for the twelve months ended June 30, 2024. The Company also generated $0.1 of cash for operating activities during the twelve months ended June 30, 2025.

Based upon the Company's current operating plans, the Company believes that its existing cash and cash equivalents will be sufficient to continue funding its development activities through the second quarter of fiscal year 2027, which is more than twelve months from the date these consolidated financial statements are issued. Consequently, management has determined there is no substantial doubt regarding the Company's ability to continue as a going concern for the twelve month period from the date these financial statements are issued.

The Company has projected its operating capital requirements based on its current operating plan, which management believes can be effectively implemented. The operating plan incorporates several assumptions that, while considered probable, may ultimately prove to be incorrect, and the Company may use all available capital resources sooner than expected. The accompanying consolidated financial statements do not include adjustments that might result from the outcome of uncertainties and assumes the Company will continue as a going concern through the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

Although the Company has been successful in raising capital in the past, there is no assurance that it will be successful in obtaining such additional financing on terms acceptable to the Company, if at all, nor is it considered probable under the accounting standards. If the Company is unable to obtain sufficient funding on acceptable terms, it could be forced to delay, reduce, or eliminate some or all its research and development programs or commercialization activities, which could materially adversely affect its business prospects or its ability to continue operations.

Licenses and Collaborations

In January 2012, we entered into a research and license agreement with Ironwood Pharmaceuticals, Inc. ("Ironwood"), pursuant to which Ironwood was granted worldwide development and commercialization rights for BNC210. In November 2014, the parties mutually agreed to terminate this license agreement, reverting all rights to BNC210 back to us. The sole obligation to Ironwood is to pay Ironwood low to mid-single digit royalties on the net sales of BNC210, if commercialized.

In September 2014, we entered the 2014 Merck Research Collaboration and License Agreement to develop compounds targeting cognitive dysfunction associated with Alzheimer's disease and other central nervous system conditions. Pursuant to the Merck Agreement, we received upfront payments totaling $17 million, another $10 million in February 2017 when the first compound from the collaboration entered Phase 1 clinical trials, and another $15 million in March 2025 upon the first dosing of a patient in a Phase 2 clinical trial. We are also eligible to receive up to an additional $450 million in milestone payments for achievement of certain development and commercial milestones.

On March 14, 2025, the Company and Merck executed the Fifth Amendment to the Research Collaboration and License Agreement which amended the patent royalty rate set out in the Merck Agreement, such that, conditioned upon achievement of net sales thresholds set forth in the Merck Agreement, as amended, the Company will be paid royalties on net sales ranging from a low single digits percentage to a low sub-teens percentage, depending on net sales volume. There were no other changes in the transaction price during the twelve months ended June 30, 2025.

In November 2020, we entered into an IP license agreement (the "Carina Biotech License") with Carina Biotech ("Carina"). Pursuant to the Carina Biotech License, we are eligible to receive approximately $75.8 in certain development and regulatory milestone payments if Carina advances the development of the therapy to a Phase 3 trial. Carina is also obligated to pay us royalties on its net sales of licensed products, on a country-by-country and product-by-product basis, ranging from the low single digits to the mid-single digits, subject to certain specified deductions. Royalties are payable until the later of expiration of all licensed patents covering the licensed products, or expiration of all data exclusivity with respect to the licensed product. If Carina enters into one or more sublicensing agreements relating to the licensed product, we are eligible to receive a percentage of sublicensing revenues. On October 30, 2024, Carina made a milestone payment to the Company in the gross amount of A$1,000,000 which was recorded as revenue in the Consolidated Statement of Operations and Other Comprehensive Income (Loss) included in this Form 10-K.

Components of Operating Results from Continuing Operations

License Revenue

Our license revenue reflects revenue earned from customers attributed to our license agreements and the milestone payments earned thereunder.

Expenses

Our expenses since inception have consisted primarily of research and development expenses, general and administrative expenses, and other costs.

Research and Development Expenses

Our research and development expenses represent costs incurred to conduct discovery and development of our proprietary drug candidates and consist primarily of:

- personnel costs, which include salaries, benefits and share-based compensation;
- expenses incurred under agreements with outside consultants and advisors, including their fees and related travel expenses; and
- expenses incurred under agreements with third parties, including Contract Research Organizations ("CROs") that conduct research, preclinical activities, and clinical trials on our behalf, as well as Contract Manufacturing Organizations ("CMOs") that manufacture our product candidates for use in our preclinical studies and clinical trials and perform other required manufacturing activities.

We expense all research and development costs as they are incurred, with development expenses being expensed to the extent they do not meet the criteria for capitalization. To date, we have not capitalized any of our research and development costs and manage our research and development costs on a consolidated basis. Our collaboration partners typically carry the majority of the research and development expenses for out-licensed product candidates at amounts that are not known or made available to us. Therefore, our research and development expenses do not reflect a complete picture of all financial resources devoted to our product candidates, nor do historical research and development expenses necessarily reflect the stage of development for particular product candidates or development projects.

Substantially all our direct research and development expenses during the twelve months ended June 30, 2025 and 2024 were on BNC210 and consisted primarily of external costs, such as consultants, CROs that conduct research and development activities on our behalf, costs related to production of preclinical and clinical materials, including fees paid to CMOs, and laboratory and vendor expenses related to the execution of our ongoing and planned preclinical studies and clinical trials. We deploy our personnel resources across all our research and development activities.

Because of the numerous risks and uncertainties associated with product development and the current stage of development of our product candidates, we cannot reasonably estimate or know the nature, timing, and estimated costs necessary to complete the remainder of the development of our product candidates. We are also unable to predict if, when, or to what extent we will obtain approval and generate revenues from the commercialization and sale of our product candidates. The duration, costs, and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, including:

- successful completion of our planned Phase 3 clinical trials in SAD and PTSD.
- successful completion of preclinical studies and of clinical trials for BNC210 and our other current product candidates and any future product candidates;
- data from our clinical programs that support an acceptable risk-benefit profile of our product candidates in the intended patient populations;
- acceptance by the FDA, regulatory authorities in Europe, or other regulatory agencies, of the IND applications, clinical trial applications and/or other regulatory filings for BNC210, our other current product candidates and any future product candidates;
- expansion and maintenance of a workforce of experienced scientists and others to continue to develop our product candidates;

•successful application for and receipt of marketing approvals from applicable regulatory authorities;

•obtainment and maintenance of regulatory exclusivity for our product candidates;

•arrangements with third-party manufacturers for, or establishment of, commercial manufacturing capabilities;

•establishment of sales, marketing and distribution capabilities and successful launch of commercial sales of our products, if and when approved, whether alone or in collaboration with others;

•acceptance of our products, if and when approved, by patients, the medical community and third-party payors;

•effective competition with other therapies;

•obtainment and maintenance of coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;

•obtainment, maintenance, enforcement, defense and protection of our rights in our intellectual property portfolio;

•avoidance of infringement, misappropriation or other violations with respect to others' intellectual property or proprietary rights; and

•maintenance of a continued acceptable safety profile of our products following receipt of any marketing approvals.

We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our preclinical studies and clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current and future preclinical and clinical product candidates. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in execution of or enrollment in any of our preclinical studies or clinical trials, we could be required to expend significant additional financial resources and time on the completion of preclinical and clinical development.

Research and development activities account for a significant portion of our operating expenses. We expect our research and development expenses to increase substantially for the foreseeable future as we continue to implement our business strategy, which includes advancing BNC210 through clinical development and other product candidates into clinical development, expanding our research and development efforts, including hiring additional personnel to support our research and development efforts, and seeking regulatory approvals for our product candidates that successfully complete clinical trials. In addition, product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. The process of conducting the necessary clinical development to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain.

General and Administrative Expenses

We expect our general and administration expenses to increase over the next several years to support expanded research and development activities and operating as a U.S. public company, including costs of additional personnel, increased costs related to investor relations activities, director and officer insurance premiums, and increased fees to outside consultants, lawyers, and accountants.

Our general and administration expenses consist primarily of :

•personnel costs, which include salaries, benefits and share-based compensation;

•expenses incurred under agreements with outside consultants and advisors, including their fees and related travel expenses;

•costs relating to audit, tax, and regulatory compliance; and

•other expenses including facilities costs, legal fees, and insurance.

Other Income

Other income consists of net interest income, income from a research and development tax incentive award, foreign currency gains and losses, fair value adjustments, and other gains and losses.

The tax incentive awards relate to the Australian Government's Research and Development Tax Incentive program.

The Australian Government's Research and Development Tax Incentive program provides a refundable tax offset for up to 43.5% of eligible research and development expenditures by Australian companies with an "aggregated turnover" of less than A$20.0 million. Grants under the program have been available for our research and development activities in Australia, as well as certain activities conducted overseas that are approved by the Australian Government. Grants are calculated at the end of the fiscal year to which they relate, based on the expenses incurred in such fiscal year and included in such fiscal year's Australian income tax return after registration of the research and development activities with the relevant authorities.

Foreign Currency Exchange

Our financial results are reported in U.S. Dollars. A substantial portion of our operating expenses and other income, if any, are denominated in the Australian dollar. During the twelve months ended June 30, 2025 and 2024, we managed our exchange rate exposure principally by maintaining foreign currency cash accounts and managing our payments from the most appropriate accounts. From time to time, we may additionally use forward exchange contracts in an effort to manage certain foreign exchange rate exposures when appropriate. There were no foreign exchange contracts used during the twelve months ended June 30, 2025 and 2024. See "Quantitative and Qualitative Disclosures About Market Risk" for more information.

Results of Operations

Comparison of Fiscal Years ended June 30, 2025 and 2024

	Year Ended June 30,		Increase (Decrease)	
	2025	**2024**	**Amount**	**Percent**
License revenue	$ 15,649,448	$ -	$ 15,649,448	N/A
Research and development	(9,005,097)	(9,417,785)	(412,688)	(4.4)%
General and administrative	(7,773,442)	(8,474,591)	(701,149)	(8.3)%
Other income	291,093	2,312,890	(2,021,797)	87.4%
Loss before income tax expense	$ (837,998)	$ (15,579,486)		

License Revenue

Our license revenue increased during the twelve months ended June 30, 2025, as compared to the same period ended 2024, primarily due to the $15 million milestone payment received from the Merck Agreement in March 2025.

Research and Development Expenses

Our research and development activities during the twelve months ended June 30, 2025 and 2024, were principally focused on the advancement of BNC210. The decrease in the fiscal year ended June 30, 2025 of approximately $0.4 million as compared to the fiscal year ended June 30, 2024 was primarily due to decreased expenditures associated with the PTSD ATTUNE program of $3.0 million combined with decreased expenditures for consulting costs of $0.1 million and professional services of $0.1 million, partially offset by increases in costs associated with the SAD PREVAIL program of $2.3 million, combined with an increase in other program spend of $0.1 million and increases in headcount and other costs of $0.2 million.

In the fiscal year ended June 30, 2025, approximately 88% of the total 2025 research and development expenses related to the advancement of our BNC210-based programs. Of the 88%, approximately 13% were attributable to PSTD ATTUNE and 75% to SAD Prevail. We do not track labor associated with each program and have allocated headcount costs on a pro rata basis. Management believes the pro rata allocation results in a reasonable estimate of the headcount costs associated with each of the programs noted above.

General and Administrative Expenses

The decrease in general and administrative expenses in the fiscal year ended June 30, 2025 of $0.7 million as compared to the fiscal year ended June 30, 2024 was due to decreases in headcount-related costs of $0.3 million due to normal fluctuations in staffing levels

during the fiscal year ended June 30, 2025 and decreased insurance expense in the current year of $0.5 million, partially offset by increases in administrative costs of $0.2 million.

Other Income

The decrease in other income of $2.0 million other income for the fiscal year ended June 30, 2025, as compared to the fiscal year ended June 30, 2024, was primarily due to net changes in the fair value adjustment of our contingent consideration liability and our warrant liability of $2.0 million combined with an increase in the loss realized on foreign currency translation of $0.2 million, partially offset by an increase in the research and development incentive award of $0.2 million.

Off-Balance Sheet Arrangements

We did not have during the period presented, and we do not currently have, any off-balance sheet financing arrangements or any relationships with unconsolidated entities or financial partnerships, including entities sometimes referred to as structured finance or special purpose entities, that were established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

JOBS Act

We are an emerging growth company, as defined in the JOBS Act. We rely on certain reduced reporting and other requirements that are otherwise generally applicable to public companies. As an emerging growth company, we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, which would otherwise be required beginning with our second annual report on Form 10-K, and (ii) 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 (auditor discussion and analysis).

Liquidity and Capital Resources

We have incurred significant operating losses and negative cash flows from operations since our inception, and we anticipate that we will incur net losses for the next several fiscal years. As of June 30, 2025, we had cash and cash equivalents of $14.2 million and an accumulated deficit of $178.3 million.

The following table sets forth the primary sources and uses of cash for each of the periods presented:

Comparison of Fiscal Years ended June 30, 2025 and 2024

	Year Ended June 30,	
	2025	**2024**
Net cash provided by (used in) operating activities	$ 77,229	$ (14,680,777)
Net cash provided by financing activities	1,528,276	15,108,794
Effect of exchange rate on changes on cash, cash equivalents, and restricted cash	(3,750)	76,974
Net increase in cash, cash equivalents, and restricted cash	$ 1,601,755	$ 504,991

Operating Activities

The $14.8 million increase in net cash provided by operating activities to $0.1 million in the fiscal year ended June 30, 2025, from $14.7 million used in operating activities for fiscal year ended June 30, 2024, is primarily attributed to a $15.1 million decrease in net loss combined with a favorable $2.6 million change in the fair value adjustment associated with the contingent consideration liability and a favorable $0.3 million effect of foreign currency translation in the year ended June 30, 2025, as compared to the same period in 2024, partially offset by an unfavorable $0.7 million change in year-over year share-based compensation expense, an unfavorable $0.6 million year-over-year change in fair value adjustments associated with the warrant liability, and an unfavorable $1.9 million year-over-year change in working capital.

Financing Activities

The $13.6 million decrease in net cash provided by financing activities to $1.5 million in the fiscal year ended June 30, 2025, from $15.1 million provided by financing activities for fiscal year ended June 30, 2024, is primarily due a decrease in proceeds from the sale of our equity instruments. Financing activities in the fiscal year ended June 30, 2025 included gross proceeds of $1.9 million from the sale and issuance of shares partially offset by equity issuance costs of $0.1 million. Financing activities in the fiscal year ended

June 30, 2024 included $16.4 million of gross proceeds from the sale and issuance of shares and warrant, partially offset by equity issuance costs of $0.4 million.

On November 18, 2024, the Company entered into an At The Market Offering Agreement (the "Sales Agreement") with H.C. Wainwright & Co., LLC (the "Sales Agent"). Pursuant to the Sales Agreement, the Sales Agent will act as the Company's agent with respect to an offering and sale, at any time and from time to time, of the Company's shares of common stock (the "Shares") in an aggregate offering amount up to $11,494,900 under the Sales Agreement. Sales of the Shares under the Sales Agreement may be made from time to time, with the timing and amount of any sales to be determined by Neuphoria based on a variety of factors. Neuphoria may determine to sell some, all, or none of the Shares under the Sales agreement and may terminate the ATM facility at its discretion. Neuphoria, through the Sales Agent, may sell Shares by any lawful method deemed to be an "at-the-market offering" defined by Rule 415(a)(4) under the Securities Act of 1933, as amended. Sales made through the Sales Agreement may be made at market prices prevailing at the time of a sale or at prices related to prevailing market prices. As a result, actual sales prices may vary. Neuphoria currently intends to use the net proceeds from the ATM, together with its existing cash and cash equivalents, to fund its pipeline development and to maintain working capital and for general corporate purposes. During the fiscal year ended June 30, 2025, we issued an aggregate of 349,801 shares of common stock under the ATM facility, receiving gross proceeds in the aggregate amount of approximately $2.1 million. The current ATM program replaces previous ATM program dated May 5, 2023, between the Company and Cantor Fitzgerald & Co., which was terminated by the Company in order to proceed with the new ATM offering with the Sales Agent.

In May 2024, we entered into a Securities Purchase Agreement with Armistice Capital Master Fund Ltd. pursuant to which the Company agreed to issue and sell in a three-tranche private placement a certain number of restricted ADSs, a pre-funded warrant to purchase ADSs and an accompanying 5-year cash purchase warrant. The first tranche of the private placement closed in June 2024, resulting in aggregate gross proceeds to the Company of $7.5 million.

Funding Requirements

Any product candidates we may develop may never achieve commercialization and we anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development expenses and our general and administrative expenses will continue to increase. As a result, until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses (including share-based compensation); costs related to third-party clinical research, non-clinical research, manufacturing and development services; costs relating to the build-out of our headquarters and other offices; license payments or milestone obligations that may arise; legal and other regulatory expenses and general overhead costs.

Based upon our current operating plan, we believe that our existing cash and cash equivalents, combined with anticipated financing transactions, will be sufficient to continue funding our development activities through the second quarter of fiscal year 2027. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We will continue to require additional financing to advance our current product candidates through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. We will continue to seek funds through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing shareholders, will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our shareholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future capital requirements depend on many factors, including but not limited to:

- the scope, progress, results and costs of independently researching and developing any of our product candidates and conducting preclinical studies and clinical trials;

•the timing, receipt and amount of milestone payments, if any, from Merck under the 2014 Merck License Agreement to develop and commercialize compounds targeting cognitive dysfunction associated with Alzheimer's disease and other central nervous system conditions;

•the timing and receipt of proceeds on the exercise of the warrant and share options, if at all exercised;

•the number, indications and characteristics of the product candidates we pursue;

•the cost of manufacturing our approved drugs, if any;

•the cost of commercialization activities;

•our ability to maintain existing collaborations and to establish new collaborations, licensing or other arrangements and the financial terms of such agreements; and

•the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including litigation costs and the outcome of such litigation.

Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

If we were unable to obtain additional financing to fund our operations through successful development and commercialization of all our potential product candidates, we may be required to reduce the scope of, delay, or terminate some or all of our planned development and commercialization activities, which could harm our business. For more information as to the risks associated with our future funding requirements, see "Risk Factors."

Contractual Obligations

We do not have any long-term debt or capital lease obligations. We do have a long-term operating lease obligation for our Australian facility and a non-current warrant liability which commits us to issuing shares to a warrant holders upon the exercise of their common stock warrant.

Critical Accounting Policies

The preparation of audited financial statements and related disclosures in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the audited financial statements, and income and expenses during the periods reported. Actual results could materially differ from those estimates. See Note 2 to the audited financial statements included in *Item 8 - Financial Statements and Supplementary Data* included elsewhere in this document for critical accounting policies as of June 30, 2025.

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

Foreign Currency Risk

The following table summarizes our exposure to foreign currency risk (all of which are risks against the Australian dollar), expressed in U.S. dollars as of June 30, 2025 and 2024:

	June 30,	
	2025	2024
	(in thousands)	
Monetary items		
Cash and cash equivalents	$ 132	$ 5,533
Restricted cash	78	119
Accounts receivable, non-trade	12	192
Accounts payable	(700)	(245)
Accrued expenses and other current liabilities	(2,304)	(1,501)
Operating lease liability	(116)	(362)
Total Monetary Items	**$ (2,898)**	**$ 3,736**
Non-monetary items		
Prepaid expenses	$ 169	$ 691
Operating lease right-of-use assets, net	—	328
Intangible assets, net (goodwill)	4,550.0	6,947.0
Total Non-Monetary Items	$ 4,719	$ 7,966
Total Monetary and Non-Monetary Items	**$ 1,821**	**$ 11,702**

The following table sets forth a sensitivity analysis of our exposure to a 10% increase and decrease in the Australian dollar against the U.S. dollar. We use 10% for the sensitivity rate used when reporting foreign currency risk internally to key management personnel, which represents management's assessment of the reasonably possible change in foreign currency rates. The sensitivity analysis below includes only outstanding foreign currency denominated monetary items and adjusts their translation at the year-end for a 10% change in foreign currency rates. A positive number below indicates an increase in profit or equity where the Australian dollar strengthens 10% against the U.S. dollar. For a 10% increase or decrease of the Australian dollar against the U.S. dollar, there would be a comparable impact on the profit or equity as set out below.

	June 30,	
	2025	2024
10% increase (i)		
Profit or loss	$ 1,269,444	$ 652,388
Equity	$ 1,747,371	$ 953,433
10% decrease (i)		
Profit or loss	$ (1,714,974)	$ (652,388)
Equity	$ (1,747,371)	$ (953,433)

(i)This is attributable to the exposure to outstanding A$ net monetary assets at the end of the reporting period in the subsidiary which is denominated in USD and reflected in the foreign currency translation reserve.

Our sensitivity to foreign currency has decreased as of June 30, 2025 due primarily to a decrease in cash and cash equivalents that are denominated in Australian dollars which is a direct result of U.S. fundraising activities and the receipt of milestone revenue denominated in USD.

Credit Risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in a financial loss to us. We have adopted a policy of only dealing with creditworthy counterparties and obtaining sufficient collateral, where appropriate, as a means of mitigating the risk of financial loss from defaults. We consider all of our material counterparties to be creditworthy.

Due to the size of potential milestone payments under our license and collaboration agreement with Merck, in fiscal years when we record receivables under this agreement, Merck is likely to represent a large percentage of our trade and other receivable balance and our revenue in such fiscal years.

Liquidity Risk

Ultimate responsibility for liquidity risk management rests with our board of directors, which has approved a liquidity risk management framework for management of our short, medium and long-term funding. We manage liquidity risk by continuously monitoring forecast, actual cash flows, and matching maturity profiles of financial assets and liabilities.

Inflation

We do not believe that inflation has had a material effect on our business, financial condition, or results of operations during the twelve months ended June 30, 2025. If our costs become subject to significant inflationary pressures, this could harm our business, financial condition, and operating results.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K beginning on page F-1. An index of those financial statements is found in Item 15, Exhibits and Financial Statement Schedules, of this Annual Report on Form 10-K.

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

The resignation of Ernst & Young from its role as our independent registered public accounting firm became effective on June 14, 2024 (the "Effective Date").

Prior to their resignation during the fiscal year ended June 30, 2023 and through the Effective Date, there were no disagreements between us and Ernst & Young on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreement, if not resolved to the satisfaction of Ernst & Young, would have caused them to make reference to the subject matter of the disagreement in connection with their reports on the financial statements for such years. During the fiscal year ended June 30, 2023 and through the Effective Date, there were no reportable events (as defined in Item 304(a)(1)(v) of Regulation S-K).

On April 30, 2024, the Company appointed Wolf & Company, P.C. as our independent registered public accounting firm for U.S. reporting purposes beginning with the fiscal year ended June 30, 2024.

During the fiscal years ended June 30, 2025 and 2024, and in the subsequent interim period through the filing of this Annual Report, neither we nor anyone on our behalf consulted with Wolf & Company, P.C. regarding either:

- the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on our financial statements, and neither was a written report provided to us nor was oral advice provided to us that Wolf & Company, P.C. concluded was an important factor considered by us in reaching a decision as to the accounting, auditing or financial reporting issue; or

- any matter that was either the subject of a disagreement or reportable event as defined in Regulation S-K, Item 304(a)(1)(iv) and Item 304(a)(1)(v), respectively.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as that term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended ("Exchange Act")) that are designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of June 30, 2025. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2025, our disclosure controls and procedures were effective to accomplish their objectives at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

As required by SEC rules and regulations implementing Section 404 of the Sarbanes-Oxley Act, our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements for external reporting purposes in accordance with GAAP. Our internal control over financial reporting includes those policies and procedures that:

(1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of our company,

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors, and

(3)provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect errors or misstatements in our consolidated financial statements. Also, 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 or compliance with the policies or procedures may deteriorate. Management assessed the effectiveness of our internal control over financial reporting on June 30, 2025. In making these assessments, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control — Integrated Framework (2013). Based on our assessments and those criteria, management determined that we maintained effective internal control over financial reporting as of June 30, 2025.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to our status as an emerging growth company under the JOBS Act.

Changes in Internal Control over Financial Reporting

There were no changes in our internal controls over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act) that occurred during the period covered by this Annual Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Insider trading arrangements and policies

No directors or officers of the Company adopted or terminated a Rule 10b5-1 trading plan or a non-Rule 10b5-1 trading arrangement during fiscal year ended June 30, 2025.

A copy of the Company’s insider trading policy is filed as Exhibit 19.1 to this annual report.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The following table sets forth, as of June 30, 2025, the name, age and position of each of our current executive officers and directors.

Name	Age	Position
Executive Officers		
Spyros Papapetropoulos	52	President, Chief Executive Officer, and Director
Tim Cunningham	63	Chief Financial Officer
Non-Executive Directors		
Miles Davies[(1)]	44	Director
Alan Fisher[(1)(2)]	72	Director
Jane Ryan, Ph.D.[(1)(2)]	66	Director
David Wilson	62	Director

(1) Audit & Risk Management Committee member

(2) Nomination and Remuneration Committee member

Background of Directors and Executive Officers

The following is a brief summary of the business experience of our executive officers.

Spyridon "Spyros" Papapetropoulos, M.D., has served as our President and Chief Executive Officer since January 5, 2023. Dr. Papapetropoulos is an experienced biopharmaceutical executive, a recognized neuroscientist/neurologist, and change agent with a 25-year career focused on CNS disorders. He has held various positions of increasing responsibility at CNS-focused start-up/small, medium specialty and large biopharma companies. Since 2020, he was the Chief Medical Officer of Vigil Neuroscience Inc, a Nasdaq-listed biopharmaceutical company developing a pipeline of neuroimmune targeted therapeutics for the treatment of neurodegenerative disorders. Prior to joining Vigil, he served as Chief Development Officer, and SVP, Head of Development at Acadia Pharmaceuticals Inc., CEO at SwanBio Therapeutics, and EVP of Research & Development and Chief Medical Officer at Cavion. Before Cavion, he held senior/executive positions at Biogen Inc., Allergan plc, Pfizer Inc., and Teva Pharmaceuticals Inc. Dr. Papapetropoulos has filed multiple INDs and has overseen a broad spectrum of CNS biopharmaceutical development programs (small molecules, biologics, gene therapy), leading to successful regulatory filings (>20 INDs and multiple NDAs/BLAs) and new product launches worldwide. Dr. Papapetropoulos received his MD and PhD in Greece from the University of Patras, School of Medicine and before joining the biopharmaceutical industry served as faculty at the Department of Neurology of the University of Miami, School of Medicine.

Tim Cunningham has served as our Chief Financial Officer since July 1, 2023 through a consulting agreement entered into between the Company and Danforth Advisors LLC, or Danforth. He has served as a Chief Financial Officer Consultant at Danforth, a strategic finance and operations firm with a focus on life sciences companies, since September 2020, where he provides chief financial officer consulting services to both public and private pharma and biotechnology companies. Prior to joining Danforth, Mr. Cunningham served as Chief Financial Officer at Organogenesis (NASDAQ:ORGO), where he took the company public and helped raise over $250 million in equity and debt financing to facilitate the company's growth. He has held leadership positions with several different public and private companies over the course of his career, which began at KPMG in NY followed by PwC Boston. Mr. Cunningham holds an MBA from Boston University, a BS in Accounting from Boston College and is a CPA in the state of Florida.

Non-Employee Board Members

The following is a brief summary of the business experience of our non-employee board members.

Peter Miles Davies has served as a member of our board of directors since July 2021, and effective June 17, 2024, was appointed as a member of our Audit & Risk Management Committee. Mr. Davies has worked at Apeiron Investment Group Ltd in the Healthcare team since 2021 to 2022. Prior to that, Mr. Davies was at Rothschild & Co. from 2006 to 2021. Mr. Davies received his Master's Degree from The University of Edinburgh, Scotland. Mr. Davies' experience in the healthcare industry includes mergers and acquisitions, strategic advisory, capital raising, and restructuring transactions, which all contributed to our board of directors' conclusion that he should serve as a director of our company.

Alan Fisher, a member of the Board since September 1, 2016, was appointed Non-Executive Chair of the Board, effective from July 1, 2023. He is also Chair of the Audit and Risk Management Committee and a member of the Nomination and Remuneration

Committee. Mr. Fisher has served as the Managing Director of Fisher Corporate Advisory Pty Ltd. since 1997, where he advises public and private companies on mergers and acquisitions, public and private equity raisings, business restructuring and strategic advice. He currently serves on the board of ASX-listed company Thorney Technologies Limited (Non-Executive Director – Chair of Audit and Risk Management Committee), an investment company, since 2016. Mr. Fisher served as a Corporate Finance Partner of Coopers & Lybrand from 1974 to 1997. Mr. Fisher received his B.Com., Accounting from the University of Melbourne, Australia and is a Fellow of the Australian and New Zealand Institute of Chartered Accountants. Mr. Fisher's experience as a biopharmaceutical board member and with financing and related transactions across industries contributed to our board of directors' conclusion that he should serve as a director of our company.

Jane Ryan**,** Ph.D. has served as a member of our board of directors since October 2020. Dr. Ryan is a member of the Audit and Risk Management Committee and Chair of the Nomination and Remuneration Committee. Since January 2014, Dr. Ryan has provided executive level advisory services to biotechnology companies in connection with capital raising, business development, and mergers and acquisitions. Dr. Ryan currently serves as a non-executive director of Viral Vector Manufacturing Facility Pty Ltd. She previously served as commercial and product development advisor to BCAL Diagnostics, a cancer diagnostics company listed on the ASX. From 2014 to 2017, Dr. Ryan served as the CEO of Sementis Ltd., a public company (unlisted) developing vaccine technology. Prior to that, Dr. Ryan was an executive and division leader of product development at Biota, a biotechnology company listed on the ASX and Nasdaq, where she provided oversight to Biota's development portfolio and programs, including the negotiation and winning of a $231 million advanced development contract with the government of the United States. From 2018 to 2023, Dr. Ryan served as director of Anatara Life Sciences, an ASX listed company. Dr. Ryan has served as a director of IDT Australia Limited since January 2022, a listed company. She is also a member of the Australian Institute of Company Directors. She received her B.Sc. from the Australia National University, her Ph.D. from Macquarie University and was a Postdoctoral Fellow at Columbia University. Dr. Ryan's knowledge of our business and experience as a biopharmaceutical executive and board member contributed to our board of directors' conclusion that she should serve as a director of our company.

David Wilson has served as a member of our board of directors since June 2016. He has served as the Chairman and founding partner of WG Partners LLP, an investment banking boutique advising life sciences companies on corporate finance, mergers and acquisitions, and capital raising, since November 2011. Prior to WG Partners LLP, Mr. Wilson worked at Piper Jaffray in various roles from 2001 to 2011, including CEO of European Operations, Chairman of the Global Healthcare Team and a Member of the Global Operating Board. He was also a Managing Director of ING Investment Banking from 1999 to 2001 and the Head of Small Companies Corporate Finance at Deutsche Bank from 1998 to 1999. He is currently on the board of directors of several privately held companies, including CS Pharmaceuticals Limited, a pharmaceutical company based in the United Kingdom, since July 2021. Mr. Wilson received his Bachelor's degree from the University of Cambridge. Mr. Wilson's experience in corporate finance and capital raising in the healthcare industry contributed to our board of directors' conclusion that he should serve as a director of our company.

Board Composition

Our business and affairs are organized under the direction of our Board. The primary responsibilities of the Board are to provide oversight, strategic guidance, counseling, and direction to our management. The Board will meet on a regular basis and additionally as required. The Board consists of six members, including Alan Fisher, who served as a non-executive member of the Board from September 1, 2016, and as Chair of the Audit & Risk Management Committee, and had been appointed Non-Executive Chair of the Board, effective from 1 July 2023. Mr. Fisher is an experienced corporate advisor and public company director, with a proven track record for implementing strategies that enhance shareholder value. His main areas of expertise include mergers and acquisitions, public and private equity raising, business restructurings, and strategic advice. He is currently a Non-Executive Director and Chair of Centrepoint Alliance Limited (ASX:CAF) and a Director and Chair of the Audit and Risk Committee of Thorney Technologies Limited (ASX:TEK).

The table below shows the year in which each of our non-executive directors was most recently re-elected and the year he or she must retire from our board of directors, with his or her position up for re-election (with retiring directors eligible for re-election).

	Year Most Recently Elected	Year Required to Stand for Re-Election
Miles Davies	2024	2025
Alan Fisher	2024	2026
Jane Ryan, Ph.D.	2024	2026
David Wilson	2024	2025

In accordance with the terms of our Certificate of Incorporation, implemented as part of our December 2024 redomiciliation, we adopted a staggered board of directors, with Mr. David Wilson and Mr. Miles Davies as the Tier 1 directors who will stand for re-election by shareholders at our 2025 Annual General Meeting.

On December 16, 2022, we entered into an employment agreement with Dr. Spyros Papapetropoulos, who commenced employment with us on January 5, 2023, as President and Chief Executive Officer as well as a Director.

Board Leadership Structure

Our board of directors is currently led by our Non-Executive Chair of the Board, Alan Fisher. Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Family Relationships

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

Director Independence

As a domestic U.S. issuer, under the listing requirements and rules of Nasdaq, we are required to have a majority of independent directors on our board of directors, as well as our Audit and Risk Management Committee, which is required to consist of entirely independent directors, subject to certain phase-in schedules. Our board of directors has determined that all of our directors, other than David Wilson and Dr. Papapetropoulos, are independent directors in accordance with the listing requirements of the Nasdaq. The Nasdaq independence definition includes a series of objective tests, including that the director is not, and has not for at least three years, been one of our employees, or has engaged in, or have had a family member engage in, a number of different transactions with us. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management.

Board Responsibilities

The board of directors is our governing body, responsible for overseeing our executive leadership team in the competent and ethical operation on a day-to-day basis and assuring that the long-term interests of our shareholders are being served. Our board of directors has established delegated limits of authority, which define the matters that are delegated to management and those that require Board approval.

The responsibilities of our board of directors include:

- charting our strategic direction, approving corporate objectives in line with that strategic direction and monitoring progress towards Board approved objectives;
- approving our statement of core values and Code of Business Conduct to underpin the desired culture within the company;
- overseeing management in its implementation of our strategic objectives and instilling our values and performance generally;
- ensuring that our remuneration policies are aligned with our purpose, values, strategic objectives and risk appetite;
- monitoring compliance with regulatory requirements and ethical standards; and;
- appointing and reviewing the performance and remuneration of the Executive Chair.

Our board of directors seeks to ensure that it is cognizant of our state of development such that at any point in time its membership as a group has expertise in areas of current and future importance to us as we grow.

Periodically, our board of directors undertakes a performance evaluation of itself that:

- compares the performance of our board of directors with the requirements of our Board Charter;
- involves the Executive Chair meeting individually with each member of our board of directors to assess how Board performance may be improved; and
- effects any improvements to the Board Charter deemed necessary or desirable.

The board of directors has also typically undertaken a strategic review process once per year to review the corporate strategy and the role of our board of directors within that strategy.

Board Oversight of Risk

One of the key functions of our Board will be informed oversight of its risk management process. The Board does not anticipate having a standing risk management committee, but rather anticipates administering this oversight function directly through the Board as a whole, as well as through various standing committees of the Board that address risks inherent in their respective areas of oversight. In particular, our Board will be responsible for monitoring and assessing strategic risk exposure and our audit committee will have the responsibility to consider and discuss the combined company's major financial risk exposures and the steps its management will take to monitor and control such exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee will also monitor compliance with legal and regulatory requirements. Our remuneration committee will also assess and monitor whether our compensation plans, policies and programs comply with applicable legal and regulatory requirements.

Board Committees

Our board of directors currently has two committees, the Audit and Risk Management Committee and the Nomination and Remuneration Committee. Each of the existing members of the Audit and Risk Management Committee and Nomination and Remuneration Committee satisfy the independence requirements under Nasdaq rules.

Audit Committee

The Audit & Risk Management Committee is not a policy-making body but assists our board of directors by implementing board policy. The role of the Audit and Risk Management Committee includes assisting our board of directors with our governance and exercising of due care, diligence and skill in relation to:

- the reporting of financial information to users of financial reports;
- the application of accounting policies;
- financial management;
- the internal control system;
- the risk management system;
- the performance management system;
- the cybersecurity risk management system;
- business policies and practices;
- protection of our assets; and
- compliance with applicable laws, regulations, standards and best practice guidelines.

In addition, the Audit and Risk Management Committee will review whether management is adopting systems and processes for the above matters that are sufficient for a company of our size and stage of development.

The members of our Audit and Risk Management Committee are currently Mr. Alan Fisher (Chair), Miles Davies, and Dr. Jane Ryan. All members of our Audit and Risk Management Committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq. Our board of directors has determined that Mr. Alan Fisher qualifies as an "audit committee financial expert" (as defined by applicable SEC rules) and has the requisite financial sophistication as required under the applicable Nasdaq rules.

Compensation Committee

The primary purpose of the Compensation Committee is to support and advise our board of directors by:

•reviewing and approving corporate goals and objectives relevant to the compensation of our Chief Executive Officer, evaluating the Chief Executive Officer's performance in light of those goals and objectives, approving the grant of equity awards to the Chief Executive Officer, and recommending to the Board the Chief Executive Officer's compensation level based on this evaluation;

•reviewing and approving the compensation of all other executive officers;

•reviewing and recommending to the Board employment and severance arrangements for executive officers

•administering and making recommendations to the Board with respect to the Company's incentive compensation and equity-based compensation plans;

•reviewing, evaluating and recommending changes, if appropriate, to the remuneration for directors; and

• overseeing succession planning for positions held by executive officers, and reviewing succession planning and management development with the Board.

The members of our Compensation Committee are currently Dr. Jane Ryan (Chair) and Mr. Alan Fisher. Our board of directors has determined that each of the committee members is independent under the applicable Nasdaq rules, is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act and is an "outside director" as defined in Section 162(m) of the Code. The Compensation Committee operates under a written charter, which provides that it will undertake an annual review and evaluation of the performance of our board of directors and its committees and present to our board of directors the results of its review.

Compensation Committee Interlocks

None of the members of the Nomination and Remuneration Committee has ever been one of our officers or employees. Except for our director Dr Papapetropoulos, who current services as a director and Chief Executive Officer, none of our executive officers currently serves, or has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors.

Code of Business Conduct

We have adopted a written Code of Business Conduct Policy that applies to our directors, managers, employees and agents acting on our behalf, including our Chief Executive Officer, Chief Financial Officer, or persons performing similar functions. Our Code of Business Conduct Policy is available under the Corporate Governance section of our website at www.neuphoriatx.com. In addition, we intend to post on our website all disclosures that are required by law or Nasdaq listing standards concerning any amendments to, or waivers from, any provision of our Code of Business Conduct Policy. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this Annual Report.

Shareholder and Interested Party Communications

Shareholders and interested parties may communicate with our Board, any committee chairperson or the non-management directors as a group by writing to the board or committee chairperson in care of Neuphoria Therapeutics Inc., 100 Summit Drive, Burlington, MA 01803. Each communication will be forwarded, depending on the subject matter, to the Board, the appropriate committee chairperson or all non-management directors.

Limitations of Liability and Indemnification of Directors and Officers

Our Constitution provides that, except to the extent prohibited by law (including under the Corporations Act of Australia) and, to the extent that a director or an officer is not otherwise indemnified by us pursuant to any director and officer liability insurance policy, we will indemnify every person who is or has been a director or an officer against any liability incurred by that person as a director or an officer, unless the liability arises out of conduct on the part of the person which involves a lack of good faith or is contrary to our express instructions. To the extent that the person is not indemnified by us pursuant to any director and officer liability insurance policy, we will indemnify that person against any liability for costs and expenses incurred by the person in their capacity as director or officer in defending any legal proceedings in which judgment is given in favor of the person, or in which they were acquitted, or in connection with an application in relation to such a proceeding in which the court grants relief.

While we have obtained insurance for our directors and executive officers, we have not entered into any Deeds of Indemnity, Insurance and Access, or Indemnity Deeds, with our directors or officers.

Delinquent Section 16(a) Reports

Section 16(a) of the Securities Exchange Act of 1934 requires our directors, certain officers and any beneficial owners of more than 10% of our ordinary shares to file reports relating to their ownership and changes in ownership of our ordinary shares with the SEC by certain deadlines. Based solely on our review of copies of the reports filed with the SEC and the written representations of our directors and executive officers, we believe that all reporting requirements for fiscal year ended June 30, 2025 were complied with by each person who at any time during the fiscal year ended June 30, 2025 was a director or an executive officer or held more than 10% of our ordinary shares except for the following: our Director Mr. Miles Davies filed a Form 3 five days late, effective on July 15, 2024.

Item 11. Executive Compensation.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations, and determinations regarding future compensation programs. Actual compensation programs that we adopt following the closing of this offering may differ materially from the currently planned programs summarized in this discussion.

Summary Compensation Table

The table below sets forth certain compensation information for: (i) our principal executive officer or other individual serving in a similar capacity during our fiscal year ending June 30, 2025; (ii) our two most highly compensated executive officers other than our principal executive officers who were serving as executive officers at June 30, 2025 whose compensation exceed $100,000; and (iii) up to two additional individuals for whom disclosure would have been required but for the fact that the individual was not serving as an executive officer at June 30, 2025. Compensation information is shown for the fiscal years ending June 30, 2025 and 2024.

We sometimes refer to these individuals to as the “named executive officers” as that term is defined under Rule 3b-7 of the Securities Exchange Act. The value of share or option awards represents the grant date fair value of awards granted with respect to fiscal years 2025 and 2024 in accordance with ASC Topic 718. Pursuant to Securities and Exchange Commission rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. Our methodology, including its underlying estimates and assumptions used in calculating these values, is set forth in Note 2 to our audited financial statements for the fiscal year ended June 30, 2025.

For share awards, these shares were valued on the grant date based on the quoted trading price of the Company’s share price on such date.

2025 Summary Compensation Table

Name and Principal Position	Year	Salary	Bonus	Stock Awards	Option Awards [1]	Non-Equity Incentive Plan Compensation	Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Spyros Papapetropoulos, M.D., PhD President and Chief Executive Officer	2024	$ 525,000	$ 196,875	$ -	$ 137,206	$ -	$ -	$ 30,000	$ 889,081
Spyros Papapetropoulos, M.D., PhD President and Chief Executive Officer	2025	$ 550,000	$ 226,875	$ -	$ 123,660	$ -	$ -	$ 50,808	$ 951,343
Tim Cunningham [2] Chief Financial Officer	2024	$ -	$ -	$ -	$ -	$ -	$ -	$ 294,788	$ 294,788
Tim Cunningham Chief Financial Officer	2025	$ -	$ -	$ -	$ -	$ -	$ -	$ 254,363	$ 254,363

(1) Share options do not represent cash payments to named executive officers. Share options granted may or may not be exercised by named executive officers.
(2) Mr. Cunningham was appointed Chief Financial Officer on July 1, 2023.

Narrative to Summary Compensation Table

The objective of our executive remuneration policy and framework is to ensure that we can attract and retain high caliber executives capable of managing our operations and achieving our strategic objectives and focus these executives on outcomes necessary for success. The executives’ total remuneration package framework is comprised of a combination of:

- base pay and benefits, including for Australian employees a superannuation retirement contribution and other entitlements;
- short-term performance incentives that may be paid as shares, share options, cash or a combination thereof; and
- long-term performance incentives through participation in our employee equity plans.

Upon recommendation by the Nomination and Remuneration Committee, our board of directors reviews and approves the base pay, benefits, incentive payments and equity awards of the Executive Chair and other executives who report directly to the Executive Chair.

Executives receive their base pay and benefits structured as a Total Fixed Remuneration ("TFR") package which may be delivered as a combination of cash and prescribed non-financial benefits at the executives' discretion. Superannuation (or local equivalent) is included in TFR. There are no guaranteed base pay increases in any executive contract.

Base pay and benefit levels are reviewed annually by the Nomination and Remuneration Committee, and includes an assessment made against market comparable positions. Factors taken into account in determining an executive's remuneration include remuneration paid to executives with comparable responsibilities, duties and experience to the executive under review by competitive biotechnology companies, the executive's demonstrated record of performance, internal relativities, and the company's capacity to pay. An executive's base pay and benefit levels may also be reviewed if the position's accountabilities increase in scope and impact.

The executives named below have pre-determined bonus or equity opportunity pursuant to the Company's bonus plan; however, in addition, discretionary short-term performance incentives ("Discretionary STI Awards") may be awarded to our executives at the end of the performance review cycle upon achievement of specific board of directors approved individual and company-related key performance indicators ("KPIs"), with a weighting of 50% each. Following a performance evaluation against these KPIs, the amount of possible Discretionary STIs payable to each executive is determined by our board of directors based on the Executive Chair's recommendation. Our board of directors determines whether a Discretionary STI Award should be in share options, shares and/or cash. For the years ended June 30, 2025 and 2024, pursuant to a bonus plan, as agreed upon by the remuneration committee, and as included in the executive compensation table in this Annual Report on Form 10-K, Spyros Papapetropoulos received a bonus.

Outstanding Equity Awards at Fiscal Year End Table

The following table provides information concerning unexercised options, stock that has not vested and equity incentive plan awards outstanding as of June 30, 2025:

	Option Awards					Stock Awards			
Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested	Market Value of Shares or Units of Stock That Have Not Vested	Number of Unearned Shares, Units, or Other Rights That Have Not Vested	Market or Payout Value of Unearned Shares, Units, or Other Rights That Have Not Vested
Spyros Papapetropoulos, M.D., PhD									
President and Chief Executive Officer	3,133	-	-	$ 43.27	12/16/2028	-	$ -	-	$ -
	783	-	-	$ 43.27	3/16/2029	-	$ -	-	$ -
	783	-	-	$ 43.27	6/16/2029	-	$ -	-	$ -
	783	-	-	$ 43.27	9/16/2029	-	$ -	-	$ -
	783	-	-	$ 43.27	12/16/2029	-	$ -	-	$ -
	783	-	-	$ 43.27	3/16/2030	-	$ -	-	$ -
	783	-	-	$ 43.27	6/16/2030	-	$ -	-	$ -
	12,750	-	-	$ 5.11	4/16/2035	-	$ -	-	$ -
	-	-	783	$ 43.27	9/16/2030	-	$ -	-	$ -
	-	-	783	$ 43.27	12/16/2030	-	$ -	-	$ -
	-	-	783	$ 43.27	3/16/2031	-	$ -	-	$ -
	-	-	783	$ 43.27	6/16/2031	-	$ -	-	$ -
	-	-	783	$ 43.27	9/16/2031	-	$ -	-	$ -
	-	-	783	$ 43.27	12/16/2031	-	$ -	-	$ -
	-	-	14,250	$ 5.11	4/16/2035	-	$ -	-	$ -
Tim Cunningham									
Chief Financial Officer	-	-	-	-	-	-	$ -	-	$ -

Key Terms of Executive Employment Agreements

Remuneration and other terms of employment for the Chief Executive Officer and the other executives are formalized in the form of an executive employment contract or consultancy agreement. Major provisions of the agreements relating to remuneration are set out below:

Spyros Papapetropoulos, M.D., President and Chief Executive Officer

Effective December 16, 2022, the Company and Dr. Spyros Papapetropoulos entered into an employment agreement, the terms of which were announced to ASX on December 16, 2022 ("Initial Employment Agreement"). Under the terms of the Initial Employment Agreement, Dr. Papapetropoulos commenced as President, Chief Executive Officer and a Director of the Company effective January 5, 2023.

For administrative purposes, it was subsequently agreed that Bionomics, Inc., then a wholly owned U.S. subsidiary of Bionomics Ltd., should be party to the employment agreement. Accordingly, on January 15, 2023, the Initial Employment Agreement was terminated and a new employment agreement was entered into between Dr. Papapetropoulos and Bionomics Inc. that, in all material respects, was on the same terms as the Initial Employment Agreement, other than the contracting party ("Papapetropoulos Employment Agreement").

Under the Papapetropoulos Employment Agreement, Dr. Papapetropoulos received an initial fixed remuneration of $525,000 base salary per year, plus reimbursement for the cost of procuring health benefits in the United States, for the provision of executive services as determined by our board of directors, plus a short term incentive/bonus potential of 50% of base salary, upon meeting the applicable performance criteria established by the Compensation Committee of the Board against agreed financial, strategic, and operational targets (the "Papapetropoulos Target Bonus"). In addition, Dr. Papapetropoulos, in connection with his appointment as President, Chief Executive Officer and a Director received an initial grant of 27,067,015 (12,529 options on a post-redomiciliation basis) Options issued with an exercise price equal to the volume weighted average selling price of Shares for the five trading day period ending immediately prior to the grant date (February 21, 2023); and with 25% vesting on the 12 month anniversary of the grant date for the Options with the balance vesting on a quarterly basis over a 3-year period from that date (with acceleration in the event of a change in control and also on termination as described below). The award was subject to shareholder approval, which was obtained on February 21, 2023.

The Executive Employment Agreement with Dr. Papapetropoulos may be terminated by either party. In the event of a termination of the agreement by the company for cause or voluntary resignation without good reason, Neuphoria will pay Dr. Papapetropoulos' earned but unpaid base salary and annual bonus. In the event of a termination without cause or resignation for good reason, Neuphoria will pay severance of 1-times base salary plus a 1-time target bonus potential to be paid in equal installments over the following 12-month period, and any outstanding equity compensation awards will fully and immediately vest.

Mr. Tim Cunningham, Chief Financial Officer

In May 2023, we amended our consulting agreement with Danforth (originally entered into for consulting services in July 2021, and further amended in August 2023). Pursuant to the Danforth agreement, Danforth provides us with the CFO services of Mr. Cunningham in exchange for fees payable to Danforth. The Danforth Agreement will continue until such time as either party to it has given notice of termination pursuant thereto with cause upon 30 days prior written notice to the other party or without cause upon 60 days prior written notice. Tim Cunningham commenced as Chief Financial Officer in July 2023.

401(k) Plan

The Company does not sponsor, nor intends to sponsor in the foreseeable future, the participation of its employees in a plan established under subsection 401(k) of the U.S. Internal Revenue.

Recovery Policy

In November 2023, we adopted a policy on the recovery of erroneously awarded incentive compensation that is compliant with the Nasdaq Listing Rules. This policy is available on our website www.neuphoriatx.com under the "Corporate Governance" section of our website.

Equity Incentive Plans

The principal features of Neuphoria's equity incentive plan are summarized below. This summary is qualified in its by reference to the actual text of the applicable plan, which is or will be filed as an exhibit to the registration statement of which this prospectus is a part.

Equity Awards

The principal features of Neuphoria's equity incentive plan are summarized below. This summary is qualified in its reference to the actual text of the applicable plan, which is or will be filed as an exhibit to the registration statement of which this prospectus is a part.

Equity awards for executives and employees have been provided by, and are currently provided by, a combination of equity plans that may include the:

- •Employee Share Option Plan (“ESOP”);
- •Employee Equity Plan (“EEP”); and
- •2024 Equity Incentive Plan.

Participation in these plans is at our board of directors’ discretion and no individual has an ongoing contractual right to participate in a plan or to receive any guaranteed benefits. For key appointments, an initial allocation of equity may be offered as a component of their initial employment agreement. The structure of equity awards is under the active review of the Compensation Committee to ensure it meets good corporate practice for a company of our size, nature and company lifecycle.

The following describes the material terms of each of the plans.

2024 Equity Incentive Plan

On December 10, 2024, our board of directors adopted Neuphoria's 2024 Equity Incentive Plan (“Plan”). The material terms of the Plan are summarized below.

Purpose. The purpose of the Plan is to provide a means through which we and our affiliates may attract and retain key personnel and to provide a means whereby our and our affiliate’s directors, employees, and consultants may acquire and maintain an equity interest in the Company, or be paid incentive compensation, which may be measured by reference to the value of our shares of common stock, thereby strengthening their commitment to the success of the Company and aligning their interests with those of our stockholders.

Eligibility and administration. Employees, consultants, and directors of the Company and its affiliates, as well as prospective employees, consultants, and directors who have accepted offers of employment or consultancy from the Company or its affiliates are eligible to receive one or more types of Awards under the Plan (defined below).

The Plan is administered by the board of directors, which has complete authority to determine the employees, consultants, and/or non-employee directors who will be granted Awards under the Plan.

Subject to the terms of the Plan, the board of directors has all discretion and authority to administer the Plan and to control its operation, in accordance with the Plan’s provisions, including, but not limited to, the power to (a) determine which employees, consultants, and non-employee directors will be granted Awards, (b) prescribe the terms and conditions of the Awards (which need not be the same), (c) interpret the Plan and the Awards, (d) adopt such procedures and/or subplans deemed necessary or appropriate for the purpose of satisfying applicable foreign laws or for qualifying for favorable tax treatment under applicable foreign laws, (e) to institute and determine the terms and conditions of an award exchange program; provided, however, that the board of directors shall not implement an award exchange program without the approval of the majority of the Company’s stockholders entitled to vote at any annual or special meeting of Company’s stockholders, and (e) make whatever rules it considers appropriate for the administration and interpretation of the Plan.

The board of directors may delegate any of its authority and powers under the Plan to a committee or one or more of the Company’s officers. However, the board of directors may not delegate its authority and powers with respect to any Awards that are granted to our executive officers or directors who are subject to Section 16(b) of the Securities Exchange Act. All interpretations, determinations and decisions made by the board of directors and any delegate of the board of directors will be final and binding on all persons and will be given the maximum possible deference permitted by law.

Limitation on Awards and shares of common stock of common stock available. The maximum number of shares of common stock available for issuance under the Plan is 1,000,000 shares of common stock (the “Share Reserve”). In no event shall the maximum aggregate number of shares of common stock that may be issued under the Plan pursuant to incentive stock options exceed the Share Reserve. The Share Reserve is subject to further adjustment as provided in the Plan. In no event shall fractional shares of common stock be issued under the Plan. The maximum number of shares of common stock that may be granted under the Plan during any single fiscal year to a non-employee director, when taken together with any cash fees paid to such non-employee director during such year in respect of his or her service as a non-employee director (including service as a member or chair of any committee of the board of directors), shall not exceed $750,000 in total value (calculating the value of any such Awards based on the grant date fair value of such Awards for financial reporting purposes).

In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split, or recapitalization, appropriate adjustments will be made to (i) the class and maximum number of shares of common stock reserved for issuance under the Plan and (ii) the class and maximum number of shares of common stock that may be issued on the exercise of ISOs.

Awards. The Plan permits the board of directors to grant various types of discretionary equity compensation awards under the Plan (“*Awards*”), including:

•Incentive stock options or ISOs

•Nonqualified stock options or NSOs

•Stock appreciation rights or SARs

•Restricted stock

•Restricted stock units or RSUs

•Stock bonus awards, and

•Performance awards.

An individual who has received one or more Awards under the Plan is referred to in this summary as a "*participant*".

A brief description of each award type follows:

•ISOs and NSOs.Stock options provide for the purchase of shares of common stock in the future at an exercise price set by the board of directors on the grant date. ISOs are stock options that by their terms qualify for, and are intended to qualify for, favorable U.S. federal tax treatment. NSOs are stock options that by their terms either do not qualify for or are not intended to qualify as ISOs. The board of directors may grant ISOs only to employees of the Company or a subsidiary at the time of grant. The exercise price of each NSO will be determined by the board of directors in its discretion, but must be at least one hundred percent (100%) of the fair market value of the shares of common stock on the grant date or otherwise compliant with Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"). The exercise price of an ISO must be at least one hundred percent (100%) of the fair market value of the shares of common stock on the grant date (although in rare circumstances, the exercise price must be at least 110% of the fair market value of the shares of common stock on the grant date), except with respect to certain substitute options granted in connection with a corporate transaction. Stock options will not be exercisable after the expiration of ten (10) years from the date of grant (or five (5) years, in the case of an ISO issued to a ten percent (10%) stockholder).

•SARs. SARs entitle the participant, upon exercise, to receive an amount equal to the appreciation of the shares of common stock subject to the Award between the grant date and the exercise date. The exercise price of a SAR will not be less than 100% of the fair market value of the underlying share of common stock on the grant date (except with respect to certain substitute SARs granted in connection with a corporate transaction). SARs will not be exercisable after the expiration of ten (10) years from the grant date.

•Restricted stock and RSUs. Restricted stock is an award of nontransferable shares of common stock that remain forfeitable unless and until specified conditions are met, and which may be subject to a purchase price. RSUs are contractual promises to pay cash or deliver shares of common stock in the future, which also are forfeitable unless and until specified conditions are met. Delivery of the shares underlying RSUs may be deferred under the terms of the Award or at the election of the participant, if the board of directors permits such a deferral.

•Stock bonuses. A stock bonus is the issuance of shares of common stock to a participant. The shares of common stock issued pursuant to a stock bonus typically are unrestricted, meaning that they are not subject to vesting requirements.

•Performance awards. Performance awards include any of the foregoing Awards that are granted subject to vesting and/or payment based on the attainment of specified performance goals or other criteria the board of directors may determine, which may or may not be objectively determinable. Such performance goals may be based solely by reference to our performance or the performance of a subsidiary, division, business segment or business unit, or based upon performance relative to performance of other companies or upon comparisons of any of the indicators of performance relative to performance of other companies.

•Vesting. The board of directors may determine the time and conditions under which the Award will vest and may specify partial vesting in one or more vesting tranches, which may be based solely upon continued employment or service for a specified period of time or may be based upon the achievement of specific performance goals established by the board of directors in its discretion.

For all purposes of the Plan, "vesting" of an Award shall mean:

a)For an ISO, NSO, or SAR, the time at which the participant has the right to exercise the Award.

b)For restricted stock or RSUs, the time at which all conditions for vesting, as stated in the applicable award agreement or the Plan, are satisfied.

c)For performance shares, the time at which the participant has satisfied the requirements to receive payment on such performance shares, as stated in the applicable award agreement or the Plan.

Vesting need not be uniform among Awards granted at the same time or to persons similarly situated. Vesting requirements shall be set forth in the applicable award agreement.

If the date of the vesting of any Award, other than an ISO, NSO, or SAR, held by participant who is subject to the Company's policy regarding trading of its shares of common stock by its officers and directors and the shares of common stock are not within a "window period" applicable to the participant, as determined by the Company in accordance with such policy, then the vesting of such Award shall not occur on such original vesting date and shall instead occur on the first day of the next "window period" applicable to the participant pursuant to such policy.

Certain transactions; Adjustments. In the event of (i) any dividend (other than ordinary cash dividends) or other distribution (whether in the form of cash, shares of common stock, other securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, amalgamation, consolidation, spin-off, split-up, split-off, combination, or other similar corporate transaction or event that affects the shares of common stock, or (ii) unusual or infrequently occurring events affecting the Company, any affiliate, or the financial statements of the Company or any affiliate, or changes in applicable rules, rulings, regulations or other requirements of any governmental body or securities exchange or inter-dealer quotation system, accounting principles or law, such that in either case the board of directors in its sole discretion may adjust any or all of (A) the number of shares of common stock or other securities of the Company (or number and kind of other securities or other property) that may be delivered in respect of Awards or with respect to which Awards may be granted under the Plan and (B) the terms of any outstanding Award, including, without limitation, (1) the number of shares of common stock or other securities of the Company (or number and kind of other securities or other property) subject to outstanding Awards or to which outstanding Awards relate, (2) the exercise price with respect to any Award, or (3) any applicable performance measures.

Treatment of Awards Upon a Change in Control. In the event of a "change in control" of the Company, as defined in the Plan, then unless otherwise provided in an award agreement, the board of directors may, in its sole discretion: (i) cancel awards for a cash payment equal to their fair value (as determined in the sole discretion of the board of directors), (ii) provide for the issuance of replacement awards, (iii) terminate stock options without providing accelerated vesting, (iv) immediately vest the unvested portion of any Award or (v) take any other action with respect to the awards the board of directors deems appropriate. The treatment of awards upon a change in control may vary among participants and types of awards in the board of directors' sole discretion. Awards subject to performance goals shall be settled upon a "change in control" of the Company based upon the extent to which the performance goals underlying such awards have been achieved as determined in the sole discretion of the board of directors.

Clawback provisions, transferability, and participant payments. All Awards will be subject to the provisions of any clawback policy implemented by Neuphoria Therapeutics Inc. and to the extent set forth in such clawback policy or in the applicable award agreement. With limited exceptions according to the laws of descent and distribution, Awards under the Plan are generally nontransferable prior to vesting and are exercisable only by the participant. With regard to tax withholding obligations arising in connection with Awards under the Plan and exercise price obligations arising in connection with the exercise of stock options under the Plan, the board of directors may, in its discretion, accept cash, wire transfer, or check, shares of our common stock that meet specified conditions (a market sell order) or such other consideration as it deems suitable or any combination of the foregoing.

Plan amendment and termination. The board of directors may amend, suspend, or terminate the Plan at any time; however, the Company will obtain stockholder approval of any material amendment to the Plan. No amendment, suspension or termination of the Plan can, without the consent of the participant, alter or impair any rights or obligations under his or her outstanding Award(s). No award may be granted pursuant to the Plan after the tenth (10^{th}) anniversary of the date on which our board of directors adopted the Plan.

Non-Employee Director Compensation

We paid our directors the amounts shown in the table below during the fiscal year ended June 30, 2025.

Name	Fees Earned or Paid in Cash	Stock Awards	Option Awards	Non-Equity Incentive Plan Compensation	Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Miles Davies	$ 49,914	$ 34,661	$ -	$ -	$ -	$ -	$ 84,575
Alan Fisher	$ 78,486	$ 69,322	$ -	$ -	$ 9,026	$ -	$ 156,834
Jane Ryan	$ 44,766	$ 34,661	$ -	$ -	$ 5,148	$ -	$ 84,575
David Wilson	$ 56,396	$ 34,661	$ -	$ -	$ -	$ -	$ 91,057
Aaron Weaver	$ 13,686	$ -	$ -	$ -	$ -	$ -	$ 13,686

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

The following table sets forth information regarding the beneficial ownership of our shares of common stock as of September 26, 2025, based on information known to Neuphoria, with respect to the beneficial ownership of shares of our ordinary shares by:

- each person known by us to be the beneficial owner of more than 5% of Neuphoria's ordinary shares;
- each of our named executive officers and directors; and
- each of our officers and directors as a group.

Beneficial ownership is determined according to the rules of the SEC, which generally provide that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power over that security, including options and a warrant that are currently exercisable or exercisable within 60 days.

In the table below, percentage ownership is based on 2,357,613 ordinary shares outstanding as of September 29, 2025. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, ordinary shares subject to options, warrants or other rights held by such person that are currently exercisable or will become exercisable within 60 days of September 29, 2025, are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed below is c/o Neuphoria Therapeutics Inc., 100 Summit Drive, Burlington, Massachusetts 01803. We believe, based on information provided to us, that each of the shareholders listed below has sole voting and investment power with respect to the shares beneficially owned by the shareholder unless noted otherwise, subject to community property laws where applicable.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	%
Greater than 5% Holders, Directors, and Named Executive Officers		
Robert & Eleanor Lipyanek, JT TEN	173,723	7.4%
Directors and Named Executive Officers		
Spyridon "Spyros" Papapetropoulos, M.D., PhD [1]	35,002	*
Tim Cunningham	-	-
Alan Fisher [2]	92	*
Miles Davies [3]	126	*
Jane Ryan, Ph.D. [4]	460	*
David Wilson [5]	209	*
All executive officers and directors as a group	35,889	1.5%

* less than 1%

(1)Includes (i) 9,888 shares, and (ii) 25,114 shares that Dr. Papapetropoulos has the right to acquire pursuant to options that are exercisable as of June 29, 2025, or will become exercisable within 60 days of such date.
(2)Represents shares that Mr. Fisher has the right to acquire pursuant to options that are exercisable as of June 29, 2025, or will become exercisable within 60 days of such date.
(3)Represents shares held by Mr. Davies as of June 29, 2025.
(4)Includes (i) 230 shares, and (ii) 230 shares that Dr. Ryan has the right to acquire pursuant to options that are exercisable as of June 29, 2025, or will become exercisable within 60 days of such date.
(5)Includes (i) 117 shares, and (ii) 92 shares that Mr. Wilson has the right to acquire pursuant to options that are exercisable as of June 29, 2025, or will become exercisable within 60 days of such date.

Securities Authorized for Issuance Under Equity Compensation Plans

The information contained under the heading "Director Independence" in Part II, Item 5. "*Securities Authorized for Issuance Under Equity Compensation Plans*" is incorporated by reference herein.

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

Other than as set forth below, there are no transaction or series of similar transactions since July 1, 2024, or any currently proposed transaction, to which we were or are a party in which:

- the amount involved exceeded or exceeds $120,000; or
- any of our directors or executive officers, any holder of 5% of any class of our voting capital shares or any member of his or her immediate family had or will have a direct or indirect material interest.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to such securities.

Related Party Transactions

Our Audit & Risk Management Committee is responsible for reviewing and monitoring the propriety of related party transactions, as set out in the Audit & Risk Management Committee Charter.

In July 2021, we entered into a consulting agreement with Danforth Advisors LLC ("Danforth") to provide consulting services to the Company. The Danforth agreement was amended in May 2023, and further amended in August 2023. Pursuant to the agreement, Danforth provides us with the Chief Financial Officer services of Mr. Cunningham in exchange for fees payable to Danforth. The Danforth agreement will continue until such time as either party to it has given notice of termination pursuant thereto with cause upon 30 days prior written notice to the other party; or without cause upon 60 days prior written notice.

In December 2023, we entered into an engagement letter with WG Partners LLP to provide financial advisory services to the Company. David Wilson, a director of the Company, is the Chairman and Chief Executive Officer of WG Partners. Under the agreement, the Company must pay to WG Partners a monthly fee of $15,000 and any applicable commission. The agreement will continue until such time as a party gives 30 days prior written notice of termination to the other party. During the fiscal years ended June 30, 2025 and 2024, the Company paid WG Partners $148,971 and $189,112, respectively. We believe that this agreement is on an arms-length basis.

Director Independence

The information contained under the heading "Director Independence" in Part III, Item 10. "*Directors, Executive Officers and Corporate Governance*" is incorporated by reference herein.

Item 14. Principal Accountant Fees and Services

Our independent registered public accounting firm is Wolf & Company, P.C. ("Wolf & Company"). Wolf & Company served as our independent auditor for fiscal years 2025 and 2024, with respect to our financial statements prepared in accordance with GAAP. Ernst & Young served as our independent registered public accounting firm for part of fiscal year 2024 with respect to our financial statements prepared in accordance with International Financial Reporting Standards. The following table presents fees for professional services rendered by Wolf & Company, P.C. and Ernst & Young for fiscal years 2025 and 2024.

	Fiscal Year 2025	Fiscal Year 2024	
	Wolf & Company	Wolf & Company	Ernst & Young
Audit and review fees	$ 258,000	$ 125,000	$ 37,552
Audit-related fees	89,000	-	-
Tax fees	-	-	-
All other fees	-	-	101,669

Audit Committee Pre-Approval Policy and Procedures

Our audit committee's policy is to pre-approve all audit and permissible non-audit services provided by our independent registered public accounting firm, the scope of services provided by our independent registered public accounting firm and the fees for the services to be performed. These services may include audit services, audit-related services, tax services and other services. Pre-approval is detailed as to the particular service or category of services and is generally subject to a specific budget. Our independent registered public accounting firm and management are required to periodically report to the audit committee regarding the extent of services provided by our independent registered public accounting firm in accordance with this pre-approval, and the fees for the services performed to date.

On November 28, 2024, our audit committee adopted the Audit & Risk Management Committee Charter that sets forth the authority and procedures pursuant to which the audit committee shall pre-approve (or, where permitted under SEC rules to subsequently approve) audit and non-audit services proposed to be performed by the independent auditor.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements.

For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.

(a)(2) Financial Statement Schedules.

Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the 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	Description
2.1	Scheme Implementation Agreement, dated October 1, 2024, between Bionomics Limited and Neuphoria Therapeutics Inc. (incorporated by reference to Exhibit 2.1 to Form 8-K filed on October 1, 2024)
2.2	Amending Agreement to Scheme Implementation Agreement, dated October 24, 2024, between Bionomics Limited and Neuphoria Therapeutics Inc (incorporated by reference to Exhibit 99.1 to Form 8-K filed on November 8, 2024)
3.1	Amended and Restated Certificate of Incorporation, as filed with the Secretary of State of the State of Delaware on October 3, 2024 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on December 23, 2024)
3.2	Bylaws, dated August 2, 2024 (incorporated by reference to Exhibit 3.2 to Form 8-K filed on December 23, 2024)
10.1	Research Collaboration and License Agreement, dated June 26, 2014, by and between Bionomics Limited and Merck Sharp & Dohme Corp. (incorporated by reference to Exhibit 10.1 to Bionomics Limited's Registration Statement on Form F-1 filed on November 22, 2021)
10.2	First Amendment to Research Collaboration and License Agreement, dated October 2, 2015, by and between Bionomics Limited and Merck Sharp & Dohme Corp. (incorporated by reference to Exhibit 10.2 to Bionomics Limited's Registration Statement on Form F-1 filed on November 22, 2021)
10.3	Second Amendment to Research Collaboration and License Agreement, dated May 9, 2016, by and between Bionomics Limited and Merck Sharp & Dohme Corp. (incorporated by reference to Exhibit 10.3 to Bionomics Limited's Registration Statement on Form F-1 filed on November 22, 2021)
10.4	Third Amendment to Research Collaboration and License Agreement, dated November 8, 2016, by and between Bionomics Limited and Merck Sharp & Dohme Corp. (incorporated by reference to Exhibit 10.4 to Bionomics Limited's Registration Statement on Form F-1 filed on November 22, 2021)
10.5	Fourth Amendment to Research Collaboration and License Agreement, dated April 26, 2017, by and between Bionomics Limited and Merck Sharp & Dohme Corp. (incorporated by reference to Exhibit 10.5 to Bionomics Limited's Registration Statement on Form F-1 filed on November 22, 2021)
10.7	IP License Agreement, dated November 18, 2020, by and between Bionomics Limited and Carina Biotech Pty Ltd. (incorporated by reference to Exhibit 10.6 to Bionomics Limited's Registration Statement on Form F-1 filed on November 22, 2021)
10.8	Consultancy Agreement, dated March 18, 2019, between Bionomics Limited and Adrian Hinton (incorporated by reference to Exhibit 10.12 to Bionomics Limited's Registration Statement on Form F-1, filed on November 22, 2021)
10.9	Letter, dated June 28, 2021, amending the Consultancy Agreement dated March 18, 2019, between Bionomics Limited and Adrian Hinton (incorporated by reference to Exhibit 10.13 to Bionomics Limited's Registration Statement on Form F-1, filed on November 22, 2021)
10.10	Letter, dated July 23, 2022, amending the Consultancy Agreement dated March 18, 2019, between Bionomics Limited and Adrian Hinton (incorporated by reference to Exhibit 4.16 to Bionomics Limited's Annual Report on Form 20-F for the fiscal year ended June 30, 2023, filed on October 18, 2023 (as amended on January 17, 2024))
10.11	Letter of Appointment, dated September 3, 2008, between Bionomics Limited and Elizabeth Doolin (incorporated by reference to Exhibit 10.14 to Bionomics Limited's Registration Statement on Form F-1, filed on November 22, 2021)
10.12	Letter, dated July 1, 2020, from Bionomics Limited to Elizabeth Doolin (incorporated by reference to Exhibit 10.15 to Bionomics Limited's Registration Statement on Form F-1, filed on November 22, 2021)
10.13	Letter, dated July 1, 2021, from Bionomics Limited to Elizabeth Doolin (incorporated by reference to Exhibit 10.16 to Bionomics Limited's Registration Statement on Form F-1, filed on November 22, 2021)

10.14	Letter, dated July 1, 2022, from Bionomics Limited to Elizabeth Doolin (incorporated by reference to Exhibit 4.20 to Bionomics Limited's Annual Report on Form 20-F for the fiscal year ended June 30, 2023, filed on October 18, 2023 (as amended on January 17, 2024)
10.15	Amended and Restated Employment Agreement, dated January 15, 2023, between Spyridon "Spyros" Papapetropoulos and Bionomics Inc., (incorporated by reference to Exhibit 4.23 to Bionomics Limited's Annual Report on Form 20-F for the fiscal year ended June 30, 2023, filed on October 18, 2023 (as amended on January 17, 2024))
10.16	Consulting Agreement, dated July 2021 and amended in May 2023 and August 2023, between Danforth Advisors, LLC and Bionomics Limited, (incorporated by reference to Exhibit 4.24 to Bionomics Limited's Annual Report on Form 20-F for the fiscal year ended June 30, 2023, filed on October 18, 2023 (as amended on January 17, 2024))
10.17	Securities Purchase Agreement, dated May 31, 2024, between Bionomics Limited and Armistice Capital Master Fund Ltd., (incorporated by reference to Exhibit 99.1 to Bionomics Limited's Report of Foreign Issuer on Form 6-K filed on June 3, 2024)
10.18	Registration Rights Agreement between Bionomics Limited and Armistice Capital Master Fund Ltd., dated June 3, 2024 (incorporated by reference to Exhibit 99.2 to Bionomics Limited's Report of Foreign Issuer on Form 6-K filed on June 3, 2024)
10.19	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 99.3 to Bionomics Limited's Report of Foreign Issuer on Form 6-K filed on June 3, 2024)
10.20	Form of Accompanying Warrant (incorporated by reference to Exhibit 99.4 to Bionomics Limited's Report of Foreign Issuer on Form 6-K filed on June 3, 2024)
10.21	Engagement Letter, dated December 1, 2023, between WG Partners and Bionomics Limited (incorporated by reference to Exhibit 10.25 to Bionomics Limited's Registration Statement on Form F-1 filed on June 18, 2024)
10.22	At The Market Offering Agreement, dated as of November 18, 2024, between Bionomics Limited and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.1 to Form 8-K filed on November 18, 2024)
10.23	At The Market Offering Agreement, by and between the Registrant and H.C. Wainwright & Co., LLC, as amended (incorporated by reference to Exhibit 1.2 to Neuphoria Therapeutics Inc.'s Registration Statement on Form S-3 filed on January 6, 2025)
10.24	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 to Form 8-K filed on December 23, 2024)
10.25	Neuphoria Therapeutics Inc. 2024 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to Form 8-K filed on December 23, 2024)
10.26	Common Stock Purchase Warrant, dated December 24, 2024, issued by Neuphoria Therapeutics Inc. to Armistice Capital Master Fund Ltd (incorporated by reference to Exhibit 10.1 to Neuphoria Therapeutics Inc.'s Registration Statement on Form S-3 filed on January 6, 2025)
14.1	Code of Conduct (incorporated by reference to Exhibit 14.1 to Form 8-K filed on December 23, 2024)
19.1	Securities Trading Policy, adopted on August 14, 2018 (incorporated by reference to Exhibit 19.1 to Form 10-K filed on September 30, 2024)
23.1*	Consent of Wolf & Company P.C., independent registered public accounting firm
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Policy for Recovery of Erroneously Awarded Compensation, adopted on November 22, 2023 (incorporated by reference to Exhibit 97.1 to Form 10-K filed on September 30, 2024)
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

Item 16. Form 10-K Summary

None.

SIGNATURES

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 Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Neuphoria Therapeutics Inc.

Date: September 29, 2025	By:	*/s/ Spyridon Papapetropoulos, M.D.*
	Name:	Spyridon Papapetropoulos
	Title:	Chief Executive Officer and Director
Date: September 29, 2025	By:	*/s/ Timothy Cunningham*
	Name:	Timothy Cunningham
	Title:	Chief Financial Officer and Principal Financial Officer
Date: September 29, 2025	By;	*/s/ Miles Davies*
	Name:	Miles Davies
	Title:	Director
Date: September 29, 2025	By:	*/s/ Alan Fisher*
	Name:	Alan Fisher
	Title:	Director
Date: September 29, 2025	By:	*/s/ Jane Ryan*
	Name:	Jane Ryan
	Title:	Director
Date: September 29, 2025	By:	*/s/ David Wilson*
	Name:	David Wilson
	Title:	Director

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Neuphoria Therapeutics Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Neuphoria Therapeutics Inc. (the Company) as of June 30, 2025, and 2024, the related consolidated statements of operations and other comprehensive income (loss), changes in shareholders' equity, and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of June 30, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These 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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

Our audits included performing procedures to assess the risks of material misstatement of the 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 audits 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 audits provide a reasonable basis for our opinion.

/s/ Wolf & Company P.C.

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

Boston, Massachusetts

September 29, 2025

Neuphoria Therapeutics Inc.
Consolidated Balance Sheets

	June 30, 2025	June 30, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 14,210,745	$ 12,608,109
Accounts receivable, non-trade	11,948	126,884
Restricted cash	77,945	—
Prepaid expenses	740,193	458,765
Total current assets	15,040,831	13,193,758
Property and equipment, net	2,771	1,994
Intangible assets, net	4,804,791	5,467,522
Operating lease right-of-use assets	102,612	216,975
Restricted cash	—	78,826
Goodwill	8,638,609	8,690,018
Total assets	$ 28,589,614	$ 27,649,093
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 1,154,369	$ 2,243,662
Accrued expenses and other current liabilities	2,950,077	1,463,421
Operating lease liability	116,314	121,990
Total current liabilities	4,220,760	3,829,073
Operating lease liability, net of current portion	—	117,628
Contingent consideration	1,169,675	587,762
Deferred tax liability	495,113	963,540
Accompanying warrant liability	3,701,492	4,657,832
Other non-current liabilities	—	2,886
Total liabilities	9,587,040	10,158,721
Commitments and contingencies (Note 17)		
Shareholders' equity:		
Common stock, $0.00001 par value, 1,978,460 and 1,103,954 shares issued and outstanding at June 30, 2025 and 2024, respectively	19	11
Additional paid-in capital, net of subscription receivable	200,194,324	198,481,027
Accumulated other comprehensive loss, net of tax	(2,845,066)	(3,013,595)
Accumulated deficit	(178,346,703)	(177,977,071)
Total shareholders' equity	19,002,574	17,490,372
Total liabilities and shareholders' equity	$ 28,589,614	$ 27,649,093

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

Neuphoria Therapeutics Inc.
Consolidated Statements of Operations and Other Comprehensive Income (Loss)

	Year Ended June 30,	
	2025	2024
License revenue	$ 15,649,448	$ -
Operating expenses:		
Research and development	9,005,097	9,417,785
General and administrative	7,773,442	8,474,591
Total operating expenses	16,778,539	17,892,376
Loss from operations	(1,129,091)	(17,892,376)
Other income (loss):		
Interest income, net	166,498	220,097
Loss on foreign currency transactions	(414,996)	(209,842)
Research and development incentive award	299,905	95,215
Gain on fair value adjustments	239,686	2,207,420
Total other income	291,093	2,312,890
Loss before income tax benefit	(837,998)	(15,579,486)
Income tax benefit	468,366	87,320
Net loss	(369,632)	(15,492,166)
Other comprehensive income:		
Unrealized gain on foreign currency translation	168,529	45,188
Total other comprehensive income	168,529	45,188
Total comprehensive loss	$ (201,103)	$ (15,446,978)
Net loss per share - basic and diluted	$ (0.23)	$ (18.62)
Weighted-average common shares outstanding - basic and diluted	1,622,924	832,225

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

Neuphoria Therapeutics Inc.
Consolidated Statement of Changes in Shareholders' Equity

	Common Shares		Stock Subscription	Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Shareholders'
	Shares	Amount	Receivable	Capital	Loss	Deficit	Equity
Balance at June 30, 2023	679,970	$ 7	$ -	$ 187,554,244	$ (3,058,783)	$ (162,484,905)	$ 22,010,563
Issuance of ADS shares and pre-funded ADS warrant, net of issuance costs of $1.3 million	423,984	4	-	10,111,975	-	-	10,111,979
Share-based compensation	-	-	-	814,808	-	-	814,808
Other comprehensive income	-	-	-	-	45,188	-	45,188
Net loss	-	-	-	-	-	(15,492,166)	(15,492,166)
Balance at June 30, 2024	1,103,954	$ 11	$ -	$ 198,481,027	$ (3,013,595)	$ (177,977,071)	$ 17,490,372
Exercise of pre-funded ADS warrant	524,705	5	-	624	-	-	629
Issuance of common stock in connection with our ATM facility, net of offering costs of $0.1 million and stock subscription receivable	349,801	3	(94,685)	1,962,485	-	-	1,867,803
Share issue costs	-	-	-	(339,524)	-	-	(339,524)
Share-based compensation	-	-	-	184,397	-	-	184,397
Other comprehensive income	-	-	-	-	168,529	-	168,529
Net loss	-	-	-	-	-	(369,632)	(369,632)
Balance at June 30, 2025	1,978,460	$ 19	$ (94,685)	$ 200,289,009	$ (2,845,066)	$ (178,346,703)	$ 19,002,574

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

Neuphoria Therapeutics Inc.
Consolidated Statement of Cash Flows

	Year Ended June 30, 2025	2024
Cash flows from operating activities:		
Net loss	$ (369,632)	$ (15,492,166)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	163,772	814,808
Depreciation and amortization expense	662,890	662,991
Non-cash rent expense	114,363	113,503
Change in fair value of accompanying warrant liability	(956,340)	(338,983)
Change in fair value of contingent consideration	716,654	(1,868,437)
Effect of foreign currency remeasurement	242,348	(27,350)
Changes in assets and liabilities:		
Accounts receivable, non-trade	114,936	299,203
Prepaid expenses	(453,058)	338,713
Accounts payable	(917,663)	804,371
Accrued expenses and other current liabilities	1,486,656	277,854
Operating lease liabilities	(123,304)	(114,147)
Deferred tax liability	(468,427)	(139,173)
Contingent consideration	(133,080)	-
Other non-current liabilities	(2,886)	(11,964)
Net cash provided by (used in) operating activities	77,229	(14,680,777)
Cash flows from financing activities:		
Proceeds from the sale of equity, net of subscriptions receivable of $0.1 million and issuance costs of $0.1 million	1,528,276	-
Proceeds from the sale of equity, net of issuance costs of $1.3 million	-	10,111,979
Proceeds from the sale of accompanying warrant	-	4,996,815
Net cash provided by financing activities	1,528,276	15,108,794
Effect of exchange rate on changes on cash, cash equivalents, and restricted cash	(3,750)	76,974
Net increase in cash, cash equivalents, and restricted cash	1,601,755	504,991
Cash, cash equivalents, and restricted cash, beginning of period	12,686,935	12,181,944
Cash, cash equivalents, and restricted cash, end of period	$ 14,288,690	$ 12,686,935
Reconciliation of cash, cash equivalents, and restricted cash:		
Cash and cash equivalents	$ 14,210,745	$ 12,608,109
Restricted cash	77,945	78,826
Total cash, cash equivalents, and restricted cash	$ 14,288,690	$ 12,686,935
Supplemental cash flow data:		
Cash paid for interest expense	$ 17,433	$ 31,516
Cash paid for income tax expense	$ -	$ 51,853

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

Note 1. The Company and Basis of Presentation

Neuphoria Therapeutics Inc. (“the Company” or "Neuphoria") is a public company incorporated in Delaware. The Company is a clinical-stage biotechnology company dedicated to developing therapies that address the complex needs of individuals affected by neuropsychiatric disorders. Neuphoria is advancing the lead drug candidate, BNC210, an oral, proprietary, selective negative allosteric modulator of the α7 nicotinic acetylcholine receptor, for the acute, “as needed” treatment of social anxiety disorder ("SAD") and for chronic treatment of post-traumatic stress disorder ("PTSD"). BNC210 is a first-of-its-kind, well tolerated, broad spectrum anti-anxiety experimental therapeutic, designed to restore neurotransmitter balance in relevant brain areas, providing rapid relief from stress and anxiety symptoms without the common pitfalls of sedation, cognitive impairment, or addiction.

In addition, the Company has a strategic partnership with Merck & Co., Inc. ("Merck") with two drugs in early-stage clinical trials for the treatment of cognitive deficits in Alzheimer’s disease and other central nervous system conditions. Our pipeline also includes the α7 nicotinic acetylcholine receptor next generation and the Kv3.1/3.2 preclinical programs, both in the lead optimization development stage.

On October 1, 2024, Bionomics Limited ("Bionomics") announced its intention to redomicile from Australia to the United States via a proposed scheme of arrangement under Australian law between Bionomics and its shareholders (the “Scheme”). Implementation of the Scheme was subject to approval of Bionomics’ shareholders as well as Australian regulatory and court approvals. Bionomics’ ordinary shares, in the form of American Depositary Shares (“ADSs”) traded in the United States since listing on the Nasdaq Global Market ("Nasdaq") in December 2021 until December 23, 2024. The Scheme was approved by Bionomics shareholders and an Australian court in December 2024. On December 23, 2024, shareholders of Bionomics received a proportionate number of shares of common stock in Neuphoria for purposes of the redomiciliation. Neuphoria is the successor issuer to Bionomics and shares of Neuphoria’s common stock commenced trading on Nasdaq on December 24, 2024. All of the issued and outstanding ordinary shares of Bionomics were exchanged for newly issued shares of common stock of Neuphoria, on the basis of one share of common stock for every 2,160 ordinary shares. Shareholders of Bionomics’ ADSs (each of which represented 180 ordinary shares) were exchanged for one share of common stock for every 12 ADS held. In addition, as a result of the redomiciliation, Neuphoria issued certain options to acquire shares of common stock in Neuphoria to holders of options to acquire shares in Bionomics (“Bionomics Options”) in exchange for their Bionomics Options and issued a warrant to purchase 1,054,381 shares of common stock in Neuphoria to an institutional investor that held a warrant to purchase 12,652,572 ADSs of Bionomics (“Bionomics Warrant”), in exchange for the Bionomics Warrant.

The issued and outstanding shares and all share and earnings per share amounts of Neuphoria’s common stock as shown in this report have been adjusted in the consolidated financial statements to reflect the redomiciliation as if it had occurred on June 30, 2023.

Details of the Company’s entity structure at the end of the reporting period are as follows:

Name	Entity	Country of Incorporation
Neuphoria Therapeutics Inc.	Parent	United States
Bionomics Limited	Subsidiary	Australia
Bionomics, Inc.	Subsidiary	United States

Capital Stock

Under the Certificate of Incorporation, Neuphoria is authorized to issue up to 30,000,000 shares of common stock and 3,000,000 shares of preferred stock, par value $0.00001 per share.

Common Stock

Voting Rights. The holders of our common stock are entitled to one vote per share on all matters on which shareholders are generally entitled to vote; provided, however, that, except as otherwise required by law, holders of common stock, as such, are not entitled to vote on any amendment to the Certificate of Incorporation that relates solely to the terms of one or more outstanding series of preferred stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to the Certificate of Incorporation. Holders of our common stock do not have cumulative voting rights in the election of directors. Accordingly, the holders of a majority of the combined voting power of our common stock could, if they so choose, elect all the directors.

Dividends. Subject to the rights of the holders of any outstanding series of preferred stock, holders of common stock are entitled to receive any dividends to the extent permitted by law when, as and if declared by our board of directors.

Liquidation. Upon the dissolution, liquidation, or winding up of Neuphoria, subject to the rights of the holders of any outstanding series of preferred stock, the holders of shares of common stock are entitled to receive the assets of Neuphoria available for distribution to its stockholders ratably in proportion to the number of shares held by them.

During the twelve months ended June 30, 2025, the Company issued 524,705 shares of common stock to Armistice Capital upon exercise of their pre-funded warrant through October 2024.

Authorized but Unissued Preferred Stock

Unless required by law or by any stock exchange on which our common stock may be listed, the authorized shares of preferred stock will be available for issuance without further action by our stockholders. Delaware law does not require stockholder approval for any issuance of authorized shares. However, the listing requirements of Nasdaq, which apply as long as our common stock is listed on Nasdaq, require stockholder approval of certain issuances equal to or exceeding 20% of the combined voting power of our common stock if issued at a discount to the market price of the common stock. These additional shares may be used for a variety of corporate purposes, including future public offerings to raise additional capital, acquisitions, and employee benefit plans.

Our Certificate of Incorporation authorizes our board of directors to establish the number of shares to be included in each series of preferred stock, and to fix the designation, powers, preferences, relative participation, optional or other rights, and the qualifications, limitations or restrictions, of the shares of each series of preferred stock. Our board of directors is also able to increase or decrease the number of authorized shares of any series of preferred stock (but not below the number of shares of that series of preferred stock then outstanding) without any further vote or action by the stockholders.

Liquidity and Going Concern

As of June 30, 2025, the Company had working capital of $10.8 million, an accumulated deficit of $178.3 million, and cash and cash equivalents of $14.2 million. The Company has not generated any product revenues and has not achieved profitable operations. There is no assurance that profitable operations will ever be achieved, and, if achieved, could be sustained on a continuing basis. In addition, development activities, clinical and non-clinical testing, and commercialization of the Company's products will require significant additional financing.

The Company is subject to a number of risks similar to other life science companies, including, but not limited to, risks related to the successful discovery, development, and commercialization of product candidates, raising additional capital, development of competing drugs and therapies, protection of proprietary technology, and market acceptance of the Company's products. As a result of these and other factors and the related uncertainties, there can be no assurance of the Company's future success.

In accordance with ASC 205-40, *Going Concern*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date these consolidated financial statements are issued. The Company incurred a net loss of $0.4 million for the twelve months ended June 30, 2025 inclusive of the receipt of milestone payments associated with our research collaboration and licensing agreements (Note 12) and incurred a net loss of $15.5 million for the twelve months ended June 30, 2024. The Company also generated $0.1 million of cash for operating activities during the twelve months ended June 30, 2025.

Based upon the Company's current operating plans, the Company believes that its existing cash and cash equivalents will be sufficient to continue funding its development activities through the second quarter of fiscal year 2027, which is more than twelve months from the date these consolidated financial statements are issued. Consequently, management has determined there is no substantial doubt regarding the Company's ability to continue as a going concern for the twelve month period from the date these financial statements are issued.

The Company has projected its operating capital requirements based on its current operating plan, which management believes can be effectively implemented. The operating plan incorporates several assumptions that, while considered probable, may ultimately prove to be incorrect, and the Company may use all available capital resources sooner than expected.. The accompanying consolidated financial statements do not include adjustments that might result from the outcome of uncertainties and assumes the Company will continue as a going concern through the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

Although the Company has been successful in raising capital in the past, there is no assurance that it will be successful in obtaining such additional financing on terms acceptable to the Company, if at all, nor is it considered probable under the accounting standards. If the Company is unable to obtain sufficient funding on acceptable terms, it could be forced to delay, reduce, or eliminate some or all its

research and development programs or commercialization activities, which could materially adversely affect its business prospects or its ability to continue operations.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the U.S. ("U.S. GAAP" or "GAAP") and include the accounts of our wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

References to "$" are U.S dollars and references to "A$" are to Australian dollars.

Note 2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts and disclosure of revenue, expenses, and certain assets and liabilities at the balance sheet date. Such estimates include the performance obligations under the Company's license agreements, the collectability of receivables, valuation of goodwill and intangibles, accruals, and determining the fair value of contingent consideration and the warrant liability. Actual results may differ from such estimates.

Cash Equivalents and Restricted Cash

Cash equivalents consist of highly liquid investments purchased with original maturities of three months or less.

The Company separately classified $0.1 million of its cash as restricted cash in current assets at June 30, 2025 as the underlying facility lease expires in less than 12 months from the reporting date. These funds were previously classified as non-current at June 30, 2024. These amounts represent the security deposit associated with the Company's Australian facility.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. The Company's cash and cash equivalents and restricted cash are held by financial institutions that management believes are of high credit quality. Amounts on deposit may at times exceed federally insured limits. The Company has not experienced any losses on its deposits of cash and cash equivalents or restricted cash and its accounts are monitored by management to mitigate risk. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash, cash equivalents, and restricted cash, and bond issuers.

Fair Value of Financial Instruments

The Company uses fair value measurements to record fair value adjustments to certain financial and non-financial assets and liabilities and to determine fair value disclosures. The accounting standards define fair value, establish a framework for measuring fair value, and require disclosures about fair value measurements. Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required to be recorded at fair value, the principal or most advantageous market in which the Company would transact are considered along with assumptions that market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions, and risk of nonperformance. The accounting standard for fair value establishes a fair value hierarchy based on three levels of inputs, the first two of which are considered observable and the last unobservable, that requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. A financial instrument's categorization within the fair value hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The three levels of inputs that may be used to measure fair value are as follows:

Level 1:	Observable inputs, such as quoted prices in active markets for identical assets or liabilities.
Level 2:	Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
Level 3:	Valuations based on unobservable inputs to the valuation methodology and including data about assumptions that market participants would use in pricing the asset or liability based on the best information available under the circumstances.

Financial instruments carried at fair value include cash, cash equivalents, and restricted cash. The carrying amounts of accounts payable and accrued liabilities approximate fair value due to their relatively short maturities. See Note 3 for disclosure of other fair value measurements.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Repairs and maintenance that do not extend the life or improve an asset are expensed as incurred. Upon retirement or sale, the cost of disposed assets and their related accumulated depreciation are removed from the balance sheet. Any gain or loss is credited or charged to operations.

The useful lives of the property and equipment are as follows:

Category	Estimated Useful Life
Furniture and office equipment	5 Years
Computer equipment	3 Years

Depreciation expense for each of the twelve months ended June 30, 2025 and 2024 was less than $0.1 million.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for indications of possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amounts to the future undiscounted cash flows attributable to these assets. An impairment loss is recognized to the extent an asset group is not recoverable, and the carrying amount exceeds the fair value. There were no impairments of long-lived assets for the twelve months ended June 30, 2025 and 2024, respectively.

Leases

The Company determines if an arrangement is a lease at inception. Right-of-Use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. The classification of the Company's leases as operating or finance leases along with the initial measurement and recognition of the associated ROU assets and lease liabilities is performed at the lease commencement date. The measurement of lease liabilities is based on the present value of future lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of future lease payments. The ROU asset is based on the measurement of the lease liability and includes any lease payments made prior to or on lease commencement and excludes lease incentives and initial direct costs incurred, as applicable. The lease terms may include options to extend or terminate the lease when it is reasonably certain the Company will exercise any such options. Rent expense for the Company's operating leases is recognized on a straight-line basis over the lease term. Amortization expense for the ROU asset associated with its finance leases is recognized on a straight-line basis over the term of the lease and interest expense associated with its finance leases is recognized on the balance of the lease liability using the effective interest method based on the estimated incremental borrowing rate.

The Company has lease agreements with lease and non-lease components. As allowed under Accounting Standards Codification ("ASC") Topic 842, *Leases* ("Topic 842"), the Company has elected to not separate lease and non-lease components for any leases involving real estate and office equipment classes of assets and, as a result, accounts for the lease and non-lease components as a single lease component. The Company has also elected to not apply the recognition requirement of Topic 842 to leases with a term of 12 months or less for all classes of assets.

Revenue Recognition

Under ASC Topic 606, *Revenue from Contracts with Customers* (“Topic 606”), an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the

transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company assesses its license arrangements within the scope of Topic 606 in accordance with this framework as follows:

License Revenue

The Company assesses whether the goods or services promised within each contract are distinct to identify those that are performance obligations. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. In assessing whether a promised good or service is distinct, and therefore a performance obligation, the Company considers factors such as the research, stage of development of the licensed product, manufacturing and commercialization capabilities of the customer, and the availability of the associated expertise in the general marketplace. The Company also considers the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, the Company is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company assesses if these options provide a material right to the customer and if so, they are considered performance obligations.

The transaction price is determined and allocated to the identified performance obligations in proportion to their stand-alone selling prices ("SSP") on a relative SSP basis. SSP is based on observable prices of the performance obligations or, when such prices are not observable, are estimated. The estimation of SSP may include factors such as forecasted revenues or costs, development timelines, discount rates, probabilities of technical and regulatory success, and considerations such as market conditions and entity-specific factors. In certain circumstances, the Company may apply the residual method to determine the SSP of a good or service if the SSP is considered highly variable or uncertain. The Company validates the SSP for performance obligations by evaluating whether changes in the key assumptions used to determine the SSP will have a significant effect on the allocation of arrangement consideration between multiple performance obligations.

If the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. The Company determines the amount of variable consideration by using the expected value method or the most likely amount method. The Company includes the amount of estimated variable consideration in the transaction price to the extent that it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

If an arrangement includes development, regulatory, or commercial milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

In determining the transaction price, the Company adjusts consideration for the effects of the time value of money if the timing of payments provides the Company with a significant benefit of financing. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensee and the transfer of the promised goods or services to the licensees will be one year or less. For arrangements with licenses of intellectual property that include sales-based royalties, including milestone payments based on the level of sales, and if the license is deemed to be the predominant item to which the royalties relate, the Company recognizes royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied at a point in time or over time, and if over time, recognition is based on the use of an output or input method.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs include, but are not limited to, salaries, benefits, travel, share-based compensation, consulting costs, contract research service costs, laboratory supplies and facilities, contract manufacturing costs, and costs paid to other third parties that conduct research and development activities on the Company's behalf. Amounts incurred in connection with license agreements are also included in research and development expenses.

Advance payments for goods or services to be rendered in the future for use in research and development activities are recorded as a prepaid asset and expensed as the related goods are delivered or the services are performed.

Accrued Research and Development Costs

The Company records the costs associated with research non-clinical studies, clinical trials, and manufacturing development as incurred. These costs are a significant component of the Company's research and development expenses, with a substantial portion of the Company's on-going research and development activities conducted by third-party service providers, including contract research and manufacturing organizations.

The Company accrues for expenses resulting from obligations under agreements with contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), and other outside service providers for which payment flows do not match the periods over which materials or services are provided to the Company. Accruals are recorded based on estimates of services received and efforts expended pursuant to agreements established with CROs, CMOs, and other outside service providers. These estimates are typically based on contracted amounts applied to the proportion of work performed and determined through analysis with internal personnel and external service providers as to the progress or stage of completion of the services. The Company makes significant judgments and estimates in determining the accrual balance in each reporting period. In the event advance payments are made to a CRO, CMO, or outside service provider, the payments will be recorded as a prepaid asset which will be amortized as the contracted services are performed. As actual costs become known, the Company adjusts its accruals. Inputs, such as the services performed, the number of patients enrolled, or the study duration, may vary from the Company's estimates, resulting in adjustments to research and development expense in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations. Historically, the Company has not experienced any material deviations between accrued and actual research and development expenses.

Share-based Compensation

The Company recognizes the cost of share-based awards granted to employees and non-employees based on the estimated grant-date fair values of the awards. The fair values of stock options are estimated on the date of grant using the Black-Scholes option pricing model. The value of the award is recognized as compensation expense on a straight-line basis over the requisite service period. Forfeitures are recognized when they occur, which may result in the reversal of compensation costs in subsequent periods as the forfeitures arise. Compensation expense for employee and non-employee share-based payment awards with performance conditions is recognized when the performance condition is deemed probable.

Foreign Currency Translation

For the Company's non-U.S. operations where the functional currency is the local currency, we translate assets and liabilities at exchange rates in effect at the balance sheet date and record translation adjustments in accumulated other comprehensive loss. We translate income statement amounts at average rates for the period. Transaction gains and losses are recorded in Other income in the Consolidated Statements of Operations and Other Comprehensive Income (Loss).

Income Taxes

The Company's income tax benefit includes U.S. and international income taxes. Certain items of income and expense are not reported in tax returns and financial statements in the same year. The tax effects of these differences are reported as deferred tax assets and liabilities. Deferred tax assets are recognized for the estimated future tax effects of deductible temporary differences and tax operating loss and credit carryforwards. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. Management assesses the likelihood the deferred tax assets will be recovered from future taxable income and, to the extent it believes it is more likely than not that all or a portion of deferred tax assets will not be realized, the Company establishes a valuation allowance. To the extent the Company establishes a valuation allowance or changes the amount allocated as the valuation allowance in a period, it includes a deferred tax benefit (expense) within the provision for income taxes in the Consolidated Statements of Operations and Other Comprehensive Loss.

Other Comprehensive Income (Loss)

Other comprehensive income (loss) is the change in shareholders' equity from transactions and other events and circumstances other than those resulting from investments by shareholders and distributions to shareholders. The Company's other comprehensive income (loss) is currently comprised of foreign currency translation adjustments reflecting the cumulative effect of changes in exchange rates between the foreign entity's functional currency and the reporting currency.

Recently Adopted Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures (ASU 2023-07)*. ASU 2023-07 is intended to improve reportable segment disclosure requirements, primarily through additional disclosures about significant segment expenses, including for single reportable segment entities. The standard is effective for the Company's fiscal year ended June 30, 2025. The amendments should be applied retrospectively to all prior periods presented in the financial statements. Since the Company has one reportable segment, adoption of this new standard did not have a material impact on the Company's consolidated financial statements (See Note 18).

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09, *Improvements to Income Tax Disclosures*, ("ASU 2023-09") which requires disclosure of disaggregated income taxes paid, prescribes standard categories for the components of the effective tax rate reconciliation, and modifies other income tax-related disclosures. ASU No. 2023-09 is effective for fiscal years beginning after December 15, 2024 and allows for adoption on a prospective basis, with a retrospective option. Early adoption is permitted. The Company is currently evaluating the impact of the ASU on the income tax disclosures within its consolidated financial statements.

In November 2024, the FASB issued ASU No. 2024-03, *Disaggregation of Income Statement Expenses* ("ASU 2024-03"). ASU 2024-03 requires public business entities to disclose in the notes to the financial statements, among other things, specific information about certain costs and expenses including purchases of inventory; employee compensation; and depreciation, amortization, and depletion expenses for each caption on the income statement where such expenses are included. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted, and the amendments may be applied prospectively to reporting periods after the effective date or retrospectively to all periods presented in the financial statements. The Company is evaluating the disclosure requirements related to the new standard.

Note 3. Fair Value Measurement

The Company measures and reports certain financial instruments as assets and liabilities at fair value on a recurring basis. The following tables set forth the fair value of the Company's liabilities at fair value on a recurring basis based on the three-tier fair value hierarchy:

	June 30, 2025			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Contingent consideration	$ -	$ -	$ 1,169,675	$ 1,169,675
Accompanying warrant liability	-	-	3,701,492	3,701,492
Total liabilities measured at fair value	$ -	$ -	$ 4,871,167	$ 4,871,167

	June 30, 2024			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Contingent consideration	$ -	$ -	$ 587,762	$ 587,762
Accompanying warrant liability	-	-	4,657,832	4,657,832
Total liabilities measured at fair value	$ -	$ -	$ 5,245,594	$ 5,245,594

The Company has no financial assets that are measured at fair value. The liabilities measured at fair value at the end of each reporting period are contingent consideration and the accompanying warrant liability. The value of financial assets and other financial liabilities approximate their fair value. The following paragraph gives information about how the fair value of the financial liability is determined.

The accompanying warrant liability relates to the Company's issuance of an accompanying warrant in conjunction with a Private Placement in June 2024. The fair value of the accompanying warrant liability was based on a Black-Scholes model valuation that required inputs (see Note 10) that were both significant to the fair value measurement and unobservable. This approach resulted in a classification of the accompanying warrant liability as Level 3 of the fair value hierarchy.

See Note 16 for additional disclosure related to Contingent consideration.

The following table summarizes changes in the fair value of contingent consideration and the accompanying warrant liability, for which each fair value was determined by Level 3 inputs:

	Contingent Consideration in a Business Combination	Freestanding Financial Instruments Accompanying Warrant Liability
Balance at June 30, 2023	$ 2,456,199	$ -
Issuance of freestanding financial instruments	-	4,996,815
Change in fair value, net of foreign currency effect	(1,868,437)	(338,983)
Balance at June 30, 2024	$ 587,762	$ 4,657,832
Payment of milestone obligation to Eclipse	(134,741)	-
Change in fair value, net of foreign currency effect	716,654	(956,340)
Balance at June 30, 2025	$ 1,169,675	$ 3,701,492

The Company evaluates transfers between levels at the end of each reporting period. There were no transfers between levels during the periods presented.

Note 4. Accounts Receivable, Non-trade

Accounts receivable, non-trade consist of the following:

	June 30, 2025	June 30, 2024
Research and development incentives receivable	$ -	$ 96,154
GST receivables	11,711	30,444
Interest receivable	237	286
Total accounts receivable, non-trade	$ 11,948	$ 126,884

Note 5. Leases

In June 2021, the Company entered into a 5-year lease agreement (the "Greenhill Lease") for its Australian facility located in Dulwich, South Australia. The initial term of the lease expires in May 2026.

The Greenhill Lease requires monthly lease payments that are subject to annual increases of 3% throughout the lease term. The lease also includes two renewal options, at the election of the Company, to renew or extend the lease for additional terms of one year each. These optional periods have not been considered in the determination of the right-of-use assets or lease liabilities associated with these leases as the Company did not consider it reasonably certain it would exercise the options. Variable lease expense for the premises primarily consists of common area maintenance and other operating costs.

The following table summarizes the Company's recognition of the Greenhill lease:

	June 30, 2025
2026	$ 119,593
Less: effect of discounting	(3,279)
Present value of lease liability	$ 116,314
Current operating lease liabilities	$ 116,314
Non-current operating lease liabilities	—
Total	$ 116,314

The discount rate associated with the Greenhill lease is 3.5% and the weighted average remaining lease term is approximately one year.

The following table summarizes the effect of lease costs in the Company's consolidated statements of operations and other comprehensive income (loss):

	Year Ended June 30,	
	2025	2024
Operating lease costs		
Research and development	$ 45,902	$ 61,110
General and administrative	50,859	68,296
Total	$ 96,761	$ 129,406

Note 6. Goodwill

The following table summarizes changes in the carrying value of goodwill for the years ended June 30, 2025 and 2024, respectively:

Carrying amount at June 30, 2023	$ 8,694,186
Foreign currency exchange differences	(4,168)
Carrying amount at June 30, 2024	8,690,018
Foreign currency exchange differences	(51,409)
Carrying amount at June 30, 2025	$ 8,638,609

The Company has only one business unit: drug development. Management tests annually whether goodwill has suffered any impairment. For the purpose of impairment testing all goodwill is allocated to the drug development business unit.

The recoverable amount of the drug development business unit is determined based on a value in use calculation which uses cash flow projections based on observable market comparables for drug compounds within the business unit over a period of twenty years covering drug discovery, development, approval and marketing, and a post-tax discount rate of 20% and 24% at June 30, 2025 and 2024, respectively. The Company is currently in its research phase and a shorter-term forecast would not provide reasonable consideration of the time frame, revenue, or costs projections. The cash flow projections are weighted based on the observable market comparables probability of realizing projected milestone and royalty payments.

Management believes that the application of discounted cash flows of observable market comparables for one drug compound is reasonable to be applied to other compounds within the reporting unit at their respective development phases. Management believes that any reasonably possible change in the key assumptions on which recoverable amount is based would not cause the aggregate carrying amount to exceed the aggregate fair value of the reporting unit. No growth rates or terminal values have been included in the forecast, as the full development life cycle has been taken into account with the cashflows.

There were no impairments to goodwill during the years ended June 30, 2025 and 2024, respectively.

Note 7. Intangible Assets

Intellectual Property

As of June 30, 2023, the acquired intellectual property related to KV1.3 compound, VDA compound, MultiCore technology and cancer stem cell technology. As of June 30, 2024, the KV1.3 compound, VDA compound, and MultiCore technology intangible assets were derecognized as no future economic benefits were expected from their use or disposition. The acquired intellectual property is carried at its cost as of the date of acquisition, less accumulated amortization and impairment charges. There is currently no internally generated intellectual property capitalized.

	Cancer Stem Cell Technology
Carrying amount at June 30, 2023	$ 6,130,253
Amortization expense	(662,731)
Carrying amount at June 30, 2024	$ 5,467,522
Amortization expense	(662,731)
Carrying amount at June 30, 2025	$ 4,804,791

Acquired intellectual property with a finite life is recognized as an asset at cost and amortized on a straightline basis over its estimated useful life of 20 years.

Note 8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	June 30, 2025	June 30, 2024
Salary and benefits	$ 794,836	$ 648,858
Research and development expenses	1,656,280	134,910
Other	35,756	37,581
EDA Loan	32,750	33,120
Professional and consulting fees	152,306	297,780
Insurance	278,149	311,172
Total accrued expenses and other current liabilities	$ 2,950,077	$ 1,463,421

Note 9. Share-Based Compensation

In December 2024, Neuphoria adopted its 2024 Equity Incentive Plan ("2024 Plan"). The maximum number of shares of common stock of the Company that are available for issuance under the 2024 Plan is 1,000,000 shares. On December 24, 2024, our predecessor entity, Bionomics Limited, effected a redomiciliation through a scheme of arrangement under Australian law whereby and following which Neuphoria became the successor entity to Bionomics. As a result of the redomiciliation, Neuphoria issued certain options to acquire shares of common stock in Neuphoria to holders of options to acquire shares in Bionomics ("Bionomics Options") in exchange for their Bionomics Options. The structure of equity awards is under the active review of the Compensation Committee to ensure it meets good corporate practice for a company of our size, nature and company lifecycle. The Committee may, from time to time, grant Options, Stock Appreciation Rights, Restricted Stock, Restricted Stock Units, Stock Bonus Awards and/or Performance Awards to one or more Eligible Persons. At June 30, 2025 there were 908,789 shares available for grant under the 2024 Plan.

Equity awards for executives and employees were previously provided by a combination of equity plans that may include the:

•Employee Share Option Plan ("ESOP"); and

•Employee Equity Plan ("EEP").

Participation in these plans was at our board of directors' discretion and no individual has an ongoing contractual right to participate in a plan or to receive any guaranteed benefits. For key appointments, an initial allocation of equity was offered as a component of the recipients initial employment agreement.

The following describes the material terms of each of the historic plans.

The Bionomics Employee Equity Plan and Bionomics Employee Share Option Plan

The EEP replaced the ESOP at the Annual General Meeting held December 2, 2021.

The EEP was last amended on October 31, 2021 to provide the Company with increased flexibility to settle EEP awards offered or granted to non-Australian employees and directors by enabling it to offer and grant EEP awards that may be settled in American Depository Shares ("ADS") (at a number of ADSs that represents the appropriate number of Ordinary Shares offered or granted under the award). In addition, the amendment permits the Company to (i) determine any monetary amounts and accept payments related to the EEP or awards issued thereunder in United States dollars (or any other currency the Board deems acceptable), (ii) impose terms and conditions on the EEP or awards issued thereunder to comply with the securities and tax laws of the United States (or any other jurisdiction the Board deems appropriate), and (iii) take any other steps the Board deems necessary or desirable to settle EEP awards in ADSs.

Share-based compensation benefits have been provided to employees via the Employee Equity Plan, with the exception of share options issued to the Executive Chairman and the Chief Executive Officer which were each approved by shareholders at the General Meeting held in February 2023.

Staff eligible to participate in the plan are those who have been a full-time or part-time employee of the Company for a period of not less than six months or are members of the Board of Directors. Options are granted under the plan for no consideration and vest

equally over five years, or when vesting conditions are achieved, unless they are bonus options which vest immediately. The amounts disclosed as remuneration relating to options are the assessed fair values at grant date of those options allocated equally over the period from grant date to vesting date.

The following table summarizes the weighted-average assumptions used in calculating the fair value of the awards granted during the years ended June 30, 2025 and 2024:

	Year Ended June 30,	
	2025	**2024**
Expected term (in years)	5.8	6.4
Expected volatility	79.6%	74.2% - 80.1%
Risk-free interest	3.8%	3.2% - 3.6%
Dividend yield	-%	-%

The following table summarizes employee and non-employee stock option activity for the year ended June 30, 2025:

	Number of Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value [(1)]
Outstanding as of June 30, 2024	51,127	$ 158.52	4.18	$ -
Granted	40,500	$ 5.11	9.80	$ 80,595
Lapsed	(416)	$ 470.53	-	$ -
Outstanding as of June 30, 2025	91,211	$ 88.79	6.15	$ 80,595
Options exercisable as of June 30, 2025	64,485	$ 120.43	4.94	$ -

[(1)] The aggregate intrinsic value in this table was calculated on the positive difference, if any, between the closing price per share of the Company's common stock on June 30, 2025 of $7.10 and the per share exercise price of the underlying options.

As of June 30, 2025, there was approximately $0.1 million of unrecognized compensation cost related to unvested employee stock option awards outstanding, which is expected to be recognized as expense over a weighted average period of 0.76 years.

During the twelve months ended June 30, 2025 and 2024, the Company recognized total share-based compensation expense of approximately $0.2 million and $0.8 million, respectively, substantially all of which was recorded as general and administrative expense in each period.

In determining the fair value of the share-based awards, the Company uses the Black-Scholes option-pricing model and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

The dividend yield of zero is based on the fact that the Company has never paid cash dividends and has no present intention to pay cash dividends. Expected volatility is estimated using the historical volatility of the Company commencing with its direct listing on the NASDAQ exchange post-redomiciliation. The Company has estimated the expected life of its stock options using the "simplified" method, whereby, the expected life equals the average of the vesting term and the original contractual term of the option for service-based awards since the Company doesn't have sufficient historical or implied data of its own. The risk-free interest rates for periods within the expected life of the option are based on the yields of zero-coupon United States Treasury securities.

Restricted Stock Units

Terms of RSUs agreements, including vesting requirements, are determined by the board of directors or its compensation committee, subject to the provisions of the 2024 Plan. RSUs granted by the Company vest according to the terms of the underlying grant agreement and are awarded at the closing stock share price on the date of grant. In the event the recipients employment with the Company terminates, any unvested underlying shares are forfeited and revert to the 2024 Plan. RSUs are not included in issued and outstanding common stock until vested and the underlying shares are released.

The table below summarizes activity relating to RSUs for the twelve months ended June 30, 2025:

	Number of Underlying Shares	Weighted-Average Grant Date Fair Value
Outstanding at June 30, 2024	-	$ -
Granted	33,915	5.11
Outstanding at June 30, 2025	33,915	$ 5.11

There were no RSUs vested at June 30, 2025. The Company recognized $0.1 million of stock-based compensation expense associated with the RSUs for the twelve months ended June 30, 2025. As of June 30, 2025, the outstanding RSUs had unamortized stock-based compensation expense of $0.1 million with a weighted-average remaining recognition period of 0.42 years and an aggregate intrinsic value of $0.2 million.

Note 10. Private Placement

On May 31, 2024, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with a select institutional accredited investor (the "Investor"), pursuant to which the Company agreed to issue and sell to the Investor in a three-tranche private placement (the "Private Placement") of American Depositary Shares with each ADS representing 180 ordinary shares of the Company, no par value per share, or pre-funded warrant to purchase ADSs (the "pre-funded warrant") in lieu thereof, and an accompanying five-year cash purchase warrant (the "accompanying warrant"), related solely to the first tranche of the private placement).

The first tranche of the Private Placement consisted of 1,296,486 ADS and 6,279,905 pre-funded warrant, at a combined purchase price of $0.99 per ADS and accompanying warrant (or $0.9899 per pre-funded warrant and accompanying warrant, which is the combined purchase price of $0.99 per ADS and accompanying warrant, minus $0.0001 which is the exercise price of each pre-funded warrant) (the "Initial Purchase Price") and the accompanying five-year cash exercise warrant to purchase up to 12,652,572 ADSs at an exercise price of $0.99 per ADS (or pre-funded warrant in lieu thereof) at the Initial Purchase Price per ADS (or pre-funded warrant in lieu thereof). The first tranche of the private placement closed on June 3, 2024, resulting in aggregate gross proceeds to the Company of $7.5 million.

The second tranche of the private placement is subject to the satisfaction of regulatory milestones that, if achieved, involve the purchase by the Investor of up to an additional $25.0 million of common stock, or pre-funded warrant in lieu thereof, from the Company at the Initial Purchase Price (as converted for the effect of the redomiciliation and the related share exchange). The second tranche milestones are: the earlier of (i) receipt of formal written correspondence by the Company from the Food and Drug Administration ("FDA") following planned interactions with the FDA regarding the outcomes of the End-of-Phase 2 meeting and breakthrough designation status for BNC210 for PTSD, or (ii) December 31, 2024. These milestones were not achieved as of December 31, 2024.

The third tranche of the private placement is subject to the satisfaction of regulatory milestones that, if achieved, involves the purchase by the Investor of up to an additional $25.0 million of common stock, or pre-funded warrant in lieu thereof, from the Company at the Initial Purchase Price (as converted for the effect of the redomiciliation and the related share exchange). The third tranche milestones are: the latter of (i) completion of an interim blinded safety review of the planned BNC210 Phase-3 PTSD study, or (ii) December 31, 2025.

The third tranche purchase option will, however, become a mandatory maximum purchase by Investor during the thirty days following receipt by the Investor of a third tranche closing notice by the Company if the Company's 10-day volume-weighted average price per share is at least $96.00 with an aggregate of at least $100 million in trading volume (or such lesser amount as may be approved by the Investor).

The Securities Purchase Agreement contains customary representations and warranties and agreements of the Company and the Investor and customary indemnification rights and obligations of the parties.

In accordance with accounting principles generally accepted in the United States of America, the Company allocated the aggregate gross proceeds of $7.5 million for the first tranche of the Private Placement by first recording the accompanying warrant as a liability at its fair value and then recording the residual proceeds to the ADSs and the pre-funded ADS warrant as permanent equity on a relative fair value basis.

The accompanying warrant is a freestanding financial instrument that is not subject to ASC 480-10-25. In addition, the accompanying warrant is not considered indexed to the Company's stock as, in the event of certain fundamental transactions, the holder of the

accompanying warrant may require the Company to make a payment based on a Black-Scholes valuation, using specific inputs. As a result, the Company recorded the accompanying warrant as a liability at fair value with continuous adjustment to fair value each reporting period through the Consolidated Statements of Operations and Comprehensive Income (Loss).

The pre-funded warrant was a freestanding financial instruments that was not subject to ASC 480-10-25 and was considered indexed to the Company's stock. The Company recorded the pre-funded warrant as permanent equity with no subsequent measurement adjustments unless modification. The pre-funded warrant was exercised in full in July 2024.

The fair value of the accompanying warrant, which is required to be subsequently measured pursuant to accounting principles generally accepted in the United States of America, was calculated using a Black-Scholes calculation with the following assumptions:

	Year Ended June 30, 2025	Year Ended June 30, 2024
Expected term (in years)	4	5
Expected volatility	79.6%	59.8%
Risk-free interest	3.7%	4.1%
Dividend yield	-%	-%

Direct and incremental costs related to the accompanying warrant was expensed as incurred. Direct and incremental costs related to the pre-funded warrant was recorded as reductions in the related proceeds.

Note 11. Warrants

The following table summarizes warrant activity for the twelve months ended June 30, 2025:

	Number of Shares of Common Stock Underlying the Warrants	Weighted Average Exercise Price
Balance at June 30, 2024	1,579,086	$ 7.92
Exercised	(524,705)	-
Balance at June 30, 2025	1,054,381	$ 11.88

The classification, expiration date, and exercise price of the shares of common stock underlying the outstanding warrant at June 30, 2025 is as follows:

	Common Stock Underlying the Outstanding Warrant	Exercise Price	Expiration Date	Classification
Accompanying warrant	1,054,381	$ 11.88	June 2029	Liability

The weighted average remaining contractual life of the 2024 accompanying warrant outstanding at June 30, 2025 is 3.93 years.

The following table summarizes warrant activity, on the basis of the share exchange resulting from the redomiciliation, for the twelve months ended June 30, 2024:

	Ordinary Share Warrant	Weighted Average Exercise Price
Balance at June 30, 2023	65,741	$ 86.40
Expired during the year	(65,741)	86.40
Balance at June 30, 2024	-	

Note 12. License Revenue

Carina Biotech Pty Ltd

In November 2020, the Company entered into an IP license agreement (the “Carina Biotech License”) with Carina Biotech Pty Ltd ("Carina Biotech"). Pursuant to the Carina Biotech License, the Company is eligible to receive approximately $75.8 million in certain development and regulatory milestone payments if Carina Biotech advances the development of the therapy to a Phase 3 trial. Carina Biotech is also obligated to pay royalties on its net sales of licensed products, on a country-by-country and product-by-product basis, ranging from the low single digits to the mid-single digits, subject to certain specified deductions. Royalties are payable until the later of expiration of all licensed patents covering the licensed products, or expiration of all data exclusivity with respect to the licensed product. If Carina Biotech enters into one or more sublicensing agreements relating to the licensed product, we are eligible to receive a percentage of sublicensing revenues.

During October 2024, Carina Biotech made a milestone payment to the Company in the gross amount of A$1 million under the terms of the Carina Biotech License agreement. The milestone payment was due to the Company as Carina Biotech achieved the initiation of the first Phase 1 Clinical Trial (i.e., first dosing in a human subject).

Merck & Co., Inc.

In June 2014, the Company entered into a Research Collaboration and License Agreement with Merck & Co., Inc. (“Merck”) ("Merck Agreement") to develop α7 receptor PAMs targeting cognitive dysfunction associated with Alzheimer’s disease and other central nervous system conditions. Under the Merck Agreement, Merck funded certain research and development activities on a full-time equivalent (“FTE”) basis pursuant to a research plan. Merck funds current and future research and development activities, including clinical development and worldwide commercialization of any products developed from the license granted by the Company.

On March 19, 2025, the Company received a $15 million milestone payment from Merck. The payment was triggered by the initiation by Merck of a Phase 2 clinical trial to evaluate the safety and efficacy of MK-1167, an α7 nicotinic acetylcholine receptor positive allosteric modulator, for the treatment of the symptoms of Alzheimer’s disease dementia (NCT06721156). This $15 million payment marks the third milestone achieved in the collaboration with Merck. Under the agreement, as amended, Neuphoria is eligible to receive up to $450 million in additional research and commercial milestone payments for certain development and commercial milestones associated with the progress of multiple candidates, plus royalties on net sales of any licensed medicines.

The Company evaluated the Merck Agreement in accordance with the provisions of Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (“ASC 606”). The Company’s obligation under the Merck Agreement related to the residual variable consideration associated with the Merck Agreement are as follows: the Company granted to Merck an exclusive license (even as to Neuphoria and its Affiliates) in the Territory under the Bionomics Ltd. Patent Rights and Bionomics Ltd. Know-How, with a right to grant and authorize sublicenses, to research, develop, make, have made, use, offer to sell, sell, import and/or otherwise exploit Compounds and Products in the Field.

Regulatory milestone payments are triggered upon the achievement of certain research and commercial milestones. The commercial milestone payments and royalties are subject to the royalty recognition constraint whereby such amounts will be recognized as revenue upon the later of: (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the payment has been allocated has been satisfied, or partially satisfied, because the exclusive license is deemed to be the sole or predominant item to which the payments relate. As all performance obligations are satisfied, the Company will recognize royalty revenue at the date the sales occur.

On March 14, 2025, the Company and Merck executed the Fifth Amendment to the Research Collaboration and License Agreement which amended the patent royalty rate set out in the agreement, such that, conditioned upon achievement of net sales thresholds set forth in the Merck Agreement, as amended, the Company will be paid royalties on net sales ranging from a low single digits percentage to a low sub-teens percentage, depending on net sales volume. There were no other changes in the transaction price during the twelve months ended June 30, 2025.

Note 13. Income Taxes

The components of loss before income taxes for the years ended June 30, 2025 and 2024 are as follows:

	June 30,	
	2025	2024
U.S.	$ (7,111,507)	$ (1,819,496)
Non - U.S.	6,273,509	(13,759,990)
Total	$ (837,998)	$ (15,579,486)

The components of income tax benefit for the years ended June 30, 2025 and 2024 are as follows:

	June 30,	
	2025	2024
Current:		
Current - Non - U.S.	$ (61)	$ (51,853)
Total current	$ (61)	$ (51,853)
Deferred:		
Deferred - U.S.	$ 532,004	$ 118,946
Deferred - state	113,698	20,227
Deferred - Non - U.S.	(925,293)	3,999,422
Less: Change in valuation allowance	748,018	(3,999,422)
Total deferred	$ 468,427	$ 139,173
Total income tax benefit	$ 468,366	$ 87,320

A reconciliation between income tax benefit and the expected tax benefit at the statutory rate for the years ended June 30, 2025 and 2024 are as follows:

	For the Year Ended June 30,			
	2025		2024	
Loss before taxes:	$ (837,998)		$ (15,579,486)	
Income tax rate reconciliation:				
Benefit at statutory rate	$ 175,980	21.0%	$ 3,894,872	25.0%
State tax expense	113,698	13.6%	-	-
Fair value adjustment on warrant liability	200,831	24.0%	-	-
Global intangible low-taxed income inclusion	(508,437)	(60.7)%	-	-
Exempt income from government assistance (R&D)	76,615	9.1%	23,804	0.2%
Net (loss) gain arising on changes in fair value of contingent consideration	(183,079)	(21.8)%	460,297	3.0%
Share-based compensation	(11,463)	(1.4)%	(104,757)	(0.7)%
Research & development expenditures	(231,386)	(27.6)%	(54,721)	(0.4)%
Project costs	301,513	36.0%	242,820	1.6%
Temporary difference not recorded as an asset	(270,470)	(32.3)%	-	-
Withholding taxes deducted from fees overseas	(62)	-	(51,853)	(0.3)%
Effect of different tax rates of subsidiaries operating in other jurisdictions	(97,032)	(11.6)%	42,212	0.3%
Change in valuation	748,018	89.3%	(3,999,422)	(25.7)%
Decrease to state tax benefit	-	-	(357,738)	(2.3)%
RTP Eclipse true-up	154,211	18.4%	-	-
Other	(571)	(0.1)%	(8,194)	(0.1)%
Total income tax benefit	$ 468,366	55.9%	$ 87,320	0.6%

The effective income tax rate is based upon the income for the year and adjustments, if any, for the potential tax consequences, benefits, or resolutions of audits or other tax contingencies. The Company's effective tax rate for the years ended June 30, 2025 and 2024 were 55.9% and 0.6%, respectively. In December 2024, the Company completed its redomiciliation to the U.S. The company's

effective tax rate was impacted by the change in statutory rates as well as an adjustment to the Company's net deferred tax liability of its U.S. subsidiary.

The principal components of the Company's deferred tax liabilities at June 30, 2025 and 2024 are as follows:

	June 30,	
	2025	2024
Deferred tax assets:		
U.S. net operating loss	$ 962,686	$ 646,812
Non - U.S. net operating loss	23,891,685	25,697,108
Capital expenditures not deducted	1,418,616	1,168,484
Provision for leave	78,891	81,513
Accrued expenses	9,091	56,122
Patent costs	470,594	509,498
Warrant costs	-	164,725
U.S. tax credit	32,061	32,061
Other adjustments	93,152	15,942
Total deferred tax assets	26,956,776	28,372,265
Deferred tax liabilities		
Eclipse acquisition	1,312,669	1,493,727
Accrued interest income	60	71
Other adjustments	-	154,217
Total deferred tax liability	1,312,729	1,648,015
Less: Valuation allowance	26,139,160	27,687,790
Net deferred tax liability	$ 495,113	$ 963,540

In the United States, on July 4, 2025, H.R. 1, also known as the One Big Beautiful Bill Act, was signed into Law. We are evaluating the impacts of this legislation and will reflect its impact in our financial statements in fiscal year 2026. At this time, we do not anticipate the financial impact of the required changes to be material.

Deferred income taxes reflect future tax effects of temporary differences between the tax and financial reporting basis of the Corporation's assets and liabilities measured using enacted tax laws and statutory tax rates applicable to the periods when the temporary differences will affect taxable income. Certain items in the above table for the year ended June 30, 2024 have been reclassified to conform to the current year presentation. When necessary, deferred tax assets are reduced by a valuation allowance if, based on the weight of available positive and negative evidence, it is more likely than not that some portion or all the deferred tax assets will not be realized. As of June 30, 2025 and 2024, respectively, the Company has $26.1 million and $27.7 million in valuation allowance against its deferred tax assets. The decrease in the valuation allowance from 2024 to 2025 was due to a change in the statutory tax rate as well as a one time milestone payment the Company does not anticipate receiving in the foreseeable future.

At June 30, 2025, the Company had U.S. net operating losses ("NOL") carryforwards of $1.0 million with a 20-year carryforward period that starts expiring in 2032 and $2.8 million with an indefinite carryforward period, state NOL carryforwards of $2.5 million with a 20-year carryforward period that starts expiring in 2043, and Australian NOL carryforwards of $95.6 million with an indefinite carryforward period. At June 30, 2024, the Company had U.S. NOL carryforwards of $1.0 million with a 20-year carryforward period and $1.7 million with an indefinite carryforward period and state NOL carryforwards of $1.3 million with a 20-year carryforward period which would start expiring in 2043, and Australian NOL carryforwards of $155.4 million with an indefinite carryforward period.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code") if a corporation undergoes an ‘‘ownership change,’’ the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income and taxes may be limited. In general, an ‘‘ownership change’’ occurs if there is a cumulative change in the Company's ownership by ‘‘5-percent shareholders’’ that exceeds 50 percentage points over a rolling three-year period. The Company is still assessing whether an ownership change within the meaning of IRC Sections 382 and 383 has occurred to date.

ASC 740 prescribes the accounting for uncertainty in income taxes recognized in the financial statements. We regularly assess the outcome of potential examinations in each of the taxing jurisdictions when determining the adequacy of the amount of unrecognized

tax benefit recorded. We recognize tax benefits from uncertain tax positions only if it more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such positions are then measured based on the largest benefit which is more likely than not to be realized upon ultimate settlement. As of June 30, 2025, the Company has no uncertain tax positions.

The Company files taxes in Australia, the U.S., and the Commonwealth of Massachusetts. The Company is not currently under audit for the open years 2021 - 2024 in the U.S. or Massachusetts. Carryforward attributes that were generated in earlier periods remain subject to examination to the extent the year in which they were used or will be used remains open for examination. The Company is not currently under audit for the open years 2020 - 2024 in Australia.

Note 14. Loss per Share

The following potential shares of common stock are anti-dilutive and are therefore excluded from the weighted average number of shares of common stock for the purposes of diluted loss per share.

	June 30,	
	2025	**2024**
Options to purchase common stock	91,211	51,127
Warrant to purchase common stock	1,054,381	1,577,706

Note 15. Related Party Transactions

Share Options Issued to Directors and Other Key Management Personnel

During the twelve months ended June 30, 2025, 27,000 stock options were granted to Dr. Spyros Papapetropoulos, CEO, and 33,915 RSUs were issued to members of the board of directors.

Danforth Advisors

In July 2021, we entered into a consulting agreement with Danforth Advisors LLC (“Danforth”) to provide consulting services to the Company. The Danforth agreement was amended in May 2023, and further amended in August 2023. Pursuant to the agreement, Danforth provides us with the Chief Financial Officer services of Mr. Cunningham in exchange for fees payable to Danforth. The Danforth agreement will continue until such time as either party to it has given notice of termination pursuant thereto with cause upon 30 days prior written notice to the other party; or without cause upon 60 days prior written notice. During the fiscal years ended June 30, 2025 and 2024, the Company paid Danforth Advisors $378,631 and $734,648, respectively. We believe that this agreement is on an arms-length basis.

WG Partners LLP

In December 2023, we entered into an engagement letter with WG Partners LLP to provide financial advisory services to Neuphoria. David Wilson, a director of Neuphoria, is the Chief Executive Officer of WG Partners. Under the agreement, Neuphoria must pay to WG Partners a monthly fee of $15,000 plus any applicable commission. The agreement will continue until such time as a party gives 30 days prior written notice of termination to the other party. During the fiscal years ended June 30, 2025 and 2024, the Company paid WG Partners $148,971 and $189,112, respectively. We believe that this agreement is on an arms-length basis.

Note 16. Contingent Consideration

As a result of the acquisition of Eclipse Therapeutic, Inc (“Eclipse”) during the year ended June 30, 2013, the Company determines and recognizes at each reporting date the fair value of the additional consideration that may be payable to Eclipse security holders due to potential royalty payments based on achieving late-stage development success or partnering outcomes based on Eclipse assets. Such potential earn-out payments are recorded at fair value and include several significant estimates including adjusted revenue projections and expenses, probability of such projections, and a suitable discount rate to calculate fair value.

Due to changes in the projected inputs associated with the timing and quantum of expected cash outflows, which are in U.S. dollars, the liability increased by $0.6 million and decreased by $1.9 million during the twelve months ended June 30, 2025 and 2024, respectively. Inputs used are based on the anticipated amounts and timing of potential milestone and royalty payments from licensing agreement with Carina Biotech.

The guidance in ASC 805, *Business Combinations*, requires an acquirer to recognize contingent consideration obligations as of the acquisition date at fair value as part of the consideration transferred in exchange for the acquired business. Subsequent changes in the fair value are recognized in the Consolidated Statement of Operations and Comprehensive Income (Loss).

The following table details the change in fair value of the contingent consideration liability for the periods presented:

		Contingent Consideration in a Business Combination
Balance at June 30, 2024	$	587,762
Payment of milestone obligation to Eclipse		(134,741)
Change in fair value, net of foreign currency effect		716,654
Balance at June 30, 2025	$	1,169,675

		Contingent Consideration in a Business Combination
Balance at June 30, 2023	$	2,456,199
Change in fair value, net of foreign currency effect		(1,868,437)
Balance at June 30, 2024	$	587,762

Note 17. Commitments and Contingencies

Ironwood Pharmaceuticals, Inc.

In January 2012, the Company entered into a research and license agreement with Ironwood Pharmaceuticals, Inc. ("Ironwood") pursuant to which Ironwood was granted worldwide development and commercialization rights for BNC210. In November 2014, the parties mutually agreed to terminate this license agreement, reverting all rights to BNC210 back to the Company. The sole obligation to Ironwood is to pay Ironwood low single digit royalties on the net sales of BNC210, if commercialized. It is not practicable to estimate the future payments of any such royalties that may arise due to the stage of development of BNC210.

Severance Obligation

The Company has a contingent liability in relation to the employment agreement with Dr. Spyros Papapetropoulos for severance pay of $787,500.

Note 18. Segment Reporting

The Company operates through a single operating and reportable segment focused on the discovery and development of allosteric ion channel modulators designed to transform the lives of patients suffering from serious central nervous system (“CNS”) disorders with high unmet medical need. Ion channels serve as important mediators of physiological function in the CNS and the modulation of ion channels influences neurotransmission that leads to downstream signaling in the brain. The Company does not have significant tangible assets as its most important asset is its personnel who are located both in the U.S. and in Australia. The Company manages all business activities on a consolidated basis. The Company's Chief Operating Decision Maker ("CODM") is the Chief Executive Officer.

The accounting policies of the operating segment are as described in Note 2. The CODM evaluates the performance of the operating segment and allocates resources based on net income (loss) as reported on the consolidated statement of operations and other comprehensive income (loss). The measure of the operating segment assets is reported on the consolidated balance sheet as total assets.

The CODM uses net income (loss) to monitor budget versus actual results and to analyze cash flows in assessing performance of the segment and allocating resources. The significant segment expenses are presented on the Company’s consolidated statements of operations and other comprehensive income (loss).

Note 19. Subsequent Events

The Company has evaluated subsequent events through September 29, 2025 and has concluded that no events or transactions have occurred that require disclosure in the accompanying consolidated financial statements, except as follows:

Between July 1, 2025 and September 30, 2025, an aggregate of $3.3 million of our common stock was sold under our ATM Sales Agreement with H.C. Wainwright, as our sales agent.

On August 27, 2025 the Company granted 34,559 non-qualified stock options to Spyros Papapetropoulos at an exercise price of $8.27. The options vest on a monthly basis over a four-year period commencing August 1, 2025.

There are no other matters or circumstances that have arisen since the end of the financial year which significantly affect or may significantly affect the results of the operations of the Company.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements (Nos. 333-283306 and 333-284512) on Form S-3 and the Registration Statement (No. 333-284544) on Form S-8 of Neuphoria Therapeutics Inc. (the Company) of our report dated September 29, 2025 relating to the consolidated financial statements of the Company appearing in this Annual Report on Form 10-K of Neuphoria Therapeutics Inc. for the year ended June 30, 2025.

/s/ WOLF & COMPANY P.C.
Boston, Massachusetts

September 29, 2025

Exhibit 31.1

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

I, Spyridon Papapetropoulos, certify that:

1.I have reviewed this Annual Report on Form 10-K of Neuphoria Therapeutics Inc.;

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

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

4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 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 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: September 29, 2025

/s/ Spyridon Papapetropoulos
Spyridon Papapetropoulos
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

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

I, Tim Cunningham, certify that:

1.I have reviewed this Annual Report on Form 10-K of Neuphoria Therapeutics Inc.;

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

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

4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 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 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: September 29, 2025

/s/ Tim Cunningham

Tim Cunningham
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION

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)

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 Neuphoria Therapeutics Inc. (the "Company"), does hereby certify, to the best of such officer's knowledge, that:

The Annual Report on Form 10-K for the annual period ended June 30, 2025 (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: September 29, 2025

/s/ Spyridon Papapetropoulos
Spyridon Papapetropoulos
Chief Executive Officer and Director
(Principal Executive Officer)

This certification is made solely for the purposes of 18 U.S.C. Section 1350, subject to the knowledge standard contained therein, and not for any other purpose. A signed original of this written statement required by Section 906 has been provided to the Registrant and will be retained by the Registrant and furnished to the United States Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION

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)

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 Neuphoria Therapeutics Inc. (the "Company"), does hereby certify, to the best of such officer's knowledge, that:

The Annual Report on Form 10-K for the annual period ended June 30, 2025 (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: September 29, 2025

/s/ Tim Cunningham
Tim Cunningham
Chief Financial Officer
(Principal Financial Officer)

This certification is made solely for the purposes of 18 U.S.C. Section 1350, subject to the knowledge standard contained therein, and not for any other purpose. A signed original of this written statement required by Section 906 has been provided to the Registrant and will be retained by the Registrant and furnished to the United States Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.