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, 2026

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.)**
14 Milliston Road, Box 195, Millis, Massachusetts	**02054**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (339) 240-6066

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 $7,017,007 based on the closing price of the registrant's Common Stock on December 31, 2025, 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 17, 2026 was 5,411,334.

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 reported 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 ("U.S. GAAP" or "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," "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

Neuphoria Therapeutics Inc. is a Delaware corporation and a clinical-stage biotechnology company. Following the results of our Phase 3 AFFIRM-1 trial and the restructuring actions taken during fiscal 2026, our activities are focused on completing the proposed merger with Scancell Holdings plc ("Scancell"), preserving cash, maintaining our public-company and contractual obligations, and managing our intellectual property and economic interests in partnered programs. We are currently conducting limited active internal research and development activities focused on our alpha7 nicotinic acetylcholine receptor negative allosteric modulator portfolio.

Our lead product candidate, BNC210, is an oral, proprietary, selective negative allosteric modulator of the alpha7 nicotinic acetylcholine receptor. On October 20, 2025, we announced that AFFIRM-1, our Phase 3 trial of BNC210 for the acute treatment of social anxiety disorder ("SAD"), did not meet its primary endpoint, and secondary endpoint analysis did not show statistically significant differences or improvement over placebo. We discontinued the BNC210 SAD program and did not initiate the planned AFFIRM-2 trial. We subsequently maintained clinical readiness of the BNC210 program for post-traumatic stress disorder ("PTSD") but paused the planned SYMPHONY Phase 2b/3 trial pending the strategic transaction review process and subsequent planned merger transaction with Scancell.

During fiscal 2026, we terminated our facility leases, retained only one full-time employee, and canceled, paused, or deferred, as applicable, our major internal research and development activities, including our preclinical programs; however, we continue to operate the Company in the ordinary course with the support of personnel via consulting arrangements and external support, including our legal, accounting, and interim CEO who continued his service on this basis (as disclosed previously in our fiscal year 2026 Quarterly Reports on Form 10-Q). Additionally, our partners continue programs independently of our internal operations. These include Merck's alpha7 receptor positive allosteric modulator ("PAM") program, the KAT6 program licensed by the former Cancer Therapeutics Cooperative Research Centre ("CTx CRC") to Pfizer Inc., and Carina Biotech's ("Carina") CNA3103 program. The collaboration includes MK-4334, which has completed Phase 1 studies, and MK-1167, which was evaluated in a now-terminated Merck-led Phase 2 trial in Alzheimer's disease dementia following an interim efficacy analysis.

Proposed Merger with Scancell Holdings plc

On July 23, 2026, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with Scancell and Scancell Merger Sub, Inc., an indirect wholly owned subsidiary of Scancell ("Merger Sub"). Subject to the terms and conditions of the Merger Agreement, Merger Sub will merge with and into Neuphoria, with Neuphoria surviving the merger as an indirect wholly owned subsidiary of Scancell (the "Merger").

At the effective time of the Merger, if consummated, each outstanding share of our common stock, other than excluded shares, will be converted into the right to receive a number of Scancell American Depositary Shares determined in accordance with the Merger Agreement and one contingent value right ("CVR"). Each CVR will represent a contractual right to receive a pro rata share of certain net proceeds, if any, received after closing under the Merck agreement, the CTx CRC arrangements (including the existing KAT6 license with Pfizer), certain permitted monetizations of specified Neuphoria intellectual property, and Neuphoria's Australian research and development tax credit for the fiscal year ended June 30, 2026. There can be no assurance that any CVR holder will receive a payment.

Completion of the Merger is subject to customary closing conditions, including approval by Neuphoria's stockholders and Scancell's shareholders, effectiveness of a registration statement on Form F-4, approval of the listing of Scancell's American Depositary Shares on Nasdaq, receipt by Scancell of at least $75.0 million in gross proceeds from the concurrent financing, and Neuphoria having at least $10.0 million of closing net cash as of December 31, 2026 or the closing, if earlier. The parties announced they expect the transactions to close in late calendar 2026, but there is no assurance they will close, or when. Scancell has stated that, other than de minimis costs to maintain and enforce agreements and intellectual property, it does not intend to develop Neuphoria's non-partnered assets after closing. See Note 20, “Subsequent Events”, for a more detailed description of the proposed Merger with Scancell, as well as copies of the relevant agreements related to the proposed Merger, each of which is incorporated by reference as an exhibit to this Annual Report on Form 10-K.

Current Portfolio Status

Program or Asset	Current Status	Control and Potential Economics
BNC210 - PTSD	Program clinic-ready; no active clinical trial, only minor internal development activity. ATTUNE met its Phase 2b primary endpoint.	Neuphoria-owned. Future development would require financing and a decision to resume or partner the asset; Scancell has stated it does not intend to develop non-partnered Neuphoria assets after the Merger.
Merck alpha7 Positive Allosteric Modulators	MK-1167 Phase 2 Alzheimer's disease trial terminated; MK-4334 has completed Phase 1 studies.	Merck controls and funds development. Neuphoria may receive additional milestones and tiered royalties.
CTx CRC / Pfizer KAT6	Pfizer-controlled program entered Phase 3; Neuphoria received a A$1.416 million distribution in May 2026.	Passive interest in future CTx CRC distributions, at a blended rate of 4.65%, if any are disbursed.
Carina CNA3103	Carina-controlled LGR5-targeted CAR-T candidate in a Phase 1/2a trial in metastatic colorectal cancer.	Potential development and regulatory milestones, royalties and a share of certain sublicensing revenue.

BNC210

BNC210 is an orally administered small molecule that selectively negatively modulates the alpha7 receptor. We historically evaluated BNC210 in acute and chronic treatment settings, including SAD and PTSD. We have discontinued the SAD program; no BNC210 clinical trial is active. Clinical and preclinical results obtained before the restructuring indicated that BNC210 may have several potential attributes relative to therapies commonly used for anxiety and stressor-related disorders, 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.

BNC210 has been evaluated in 15 clinical trials involving healthy volunteers, elderly patients with agitation, and patients with generalized anxiety disorder ("GAD"), SAD, and PTSD. Across these studies, BNC210 was generally well tolerated following both acute and chronic dosing.

In prior clinical trials involving patients with GAD and healthy subjects exposed to a panic model, we observed three principal findings:

- statistically significant reductions in amygdala hyperactivity when subjects were exposed to fear-inducing triggers;
- statistically significant reductions in defensive behavior in a head-to-head study in which lorazepam did not produce a significant reduction; and
- statistically significant reductions in the intensity and total number of panic symptoms.

We developed a proprietary tablet formulation of BNC210 intended to overcome the food effect observed with the earlier liquid suspension and to provide more predictable exposure in an outpatient setting. We evaluated the tablet formulation in pharmacokinetic studies and used it in the Phase 2 PREVAIL trial in SAD, the Phase 2b ATTUNE trial in PTSD, and the Phase 3 AFFIRM-1 trial in SAD.

In December 2022, we announced results from the Phase 2 PREVAIL trial in SAD. PREVAIL did not meet its prespecified primary endpoint, although post hoc analyses showed signals that informed the Phase 3 AFFIRM-1 design. The PREVAIL results were published in Psychiatry Research in 2025. AFFIRM-1 enrolled approximately 332 adults with SAD and evaluated a single 225 mg dose of BNC210 against placebo during a public-speaking challenge. On October 20, 2025, we announced that AFFIRM-1 did not meet its primary endpoint and that its secondary efficacy analyses showed no statistically significant differences or improvement over placebo. The safety and tolerability profile was consistent with prior studies. Based on these results, we discontinued further development of BNC210 for SAD.

Before AFFIRM-1, we completed an End-of-Phase 2 meeting with the Food and Drug Administration (" FDA") regarding a potential registrational program for SAD. Those discussions are historical and we have no current plan to further develop BNC210 for SAD.

In September 2023, we announced results from ATTUNE, a double-blind, placebo-controlled Phase 2b trial conducted at 34 sites in the United States and the United Kingdom. The trial enrolled 212 patients, randomized 1:1 to receive BNC210 900 mg twice daily as monotherapy or placebo for 12 weeks. ATTUNE met its primary endpoint of change from baseline in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) total symptom severity score at Week 12 (p=0.048). Statistically significant differences were also observed at Week 4 (p=0.016) and Week 8 (p=0.015). At Week 12, BNC210 also produced statistically significant improvements in depressive symptoms measured by the Montgomery-Asberg Depression Rating Scale ("MADRS") (p=0.041) and sleep measured by the Insomnia Severity Index ("ISI") (p=0.039).

In July 2024, following an End-of-Phase 2 meeting, we announced that the FDA had provided feedback on a potential path to an NDA submission for BNC210 in PTSD that, together with ATTUNE, contemplated one additional placebo-controlled registrational trial and a 52-week open-label extension. The principal points discussed with the FDA included:

- the FDA agreed that CAPS-5 total symptom severity score and the Clinician Global Impression–Severity scale ("CGI-S") could serve as the primary and key secondary efficacy endpoints, respectively, in a proposed registrational trial;
- the proposed design contemplated evaluating the 900 mg twice-daily dose used in ATTUNE and a lower dose to further characterize the balance of efficacy and safety;
- the FDA and Neuphoria reached high-level agreement on proposed participant characteristics and the methodology for determining sample size; and
- the FDA provided guidance on a proposed hepatic monitoring plan, including monitoring for excessive alcohol consumption.

We did not initiate the planned SYMPHONY Phase 2b/3 trial. The PTSD program maintains clinical readiness, and any future development would depend on available financing and a decision by Neuphoria or a third party to resume the program. If the Merger is completed, Scancell has stated that it does not intend to develop Neuphoria's non-partnered assets, including BNC210, other than incurring de minimis intellectual-property maintenance and enforcement costs.

The FDA previously granted Fast Track designation to BNC210 for PTSD and for the acute treatment of SAD and other anxiety-related disorders. The SAD program has since been discontinued.

Partnered and Legacy Programs

Alpha7 Receptor Positive Allosteric Modulator Program with Merck

In June 2014, we entered into a research collaboration and license agreement with Merck to develop alpha7 receptor positive allosteric modulators “PAMs” targeting cognitive dysfunction associated with Alzheimer's disease and other central nervous system ("CNS") conditions. Merck controls and funds clinical development and worldwide commercialization. The collaboration includes two clinical-stage candidates: MK-1167, which was being evaluated in a Merck-led Phase 2 trial in Alzheimer's disease dementia and was terminated after a planned interim analysis due to lack of efficacy, and MK-4334, which has completed Phase 1 safety and biomarker studies.

On March 19, 2025, we received a $15.0 million milestone payment after Merck initiated the Phase 2 trial of MK-1167 (NCT06721156). Under the agreement, as amended, we may receive up to $450.0 million in additional development and commercial milestone payments associated with multiple candidates, plus tiered royalties on net sales ranging from a low-single-digit percentage to a low-sub-teens percentage, depending on net sales volume.

Because Merck controls the program and our information rights are limited, we cannot predict whether or when any future milestone will be achieved, whether any licensed medicine will be commercialized, or whether we will receive any additional milestone or royalty payments.

Discontinued Internal CNS Preclinical Programs

As part of our fiscal 2026 restructuring, we stopped active work on all internally conducted preclinical programs. These assets include next-generation alpha7 receptor negative allosteric modulators ("NAMs") and programs directed to Kv3.1/3.2 and Nav1.7/1.8 ion channels. We now incur only limited costs to maintain selected intellectual property and contractual rights. Those programs did not advance into clinical development.

We have no current plan to advance these assets internally. Any future development would require a third-party licensee, purchaser or other strategic counterparty. If the Merger is completed, Scancell has stated that it does not intend to develop Neuphoria's non-partnered assets beyond de minimis intellectual-property maintenance and enforcement activities.

Legacy Oncology and Other Partnered Assets

Through our participation in the former CTx CRC, we retain a passive economic interest in a KAT6 program licensed to Pfizer. On May 21, 2026, we received an A$1.416 million distribution after dosing began for the first subject in the first Phase 3 trial in ER-positive/HER2-negative metastatic breast cancer. Based on our past contributions, we believe we may be eligible to receive approximately 4.65% of future distributions from the relevant CTx CRC entities, if any. The 4.65% represents a blended rate across two CTx CRC programs to which the Company is a participating party. We are a passive participant and cannot determine whether future milestones will be achieved or whether or when we will receive additional distributions.

In November 2020, we exclusively licensed certain BNC101 intellectual property to Carina Biotech for the development of CAR-T and other adoptive cell therapies. 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. Carina's LGR5-targeted candidate, CNA3103, entered a Phase 1/2a trial in metastatic colorectal cancer, with patient dosing beginning in December 2023. Carina paid us an A$1.0 million milestone in October 2024. As disclosed in our Quarterly Report on Form 10-Q for the period ended March 31, 2026, we are eligible for approximately A$2.0 million of additional development and regulatory milestones if Carina advances the program to Phase 2 and A$3.0 million of additional development and regulatory milestones if Carina advances the program to Phase 3, as well as royalties on net sales and a share of certain sublicensing revenue. Carina controls development and regulatory activities.

Our other legacy oncology asset, BNC105, is a vascular-disrupting tubulin polymerization inhibitor that has been evaluated in six clinical trials. We are not actively developing BNC105 and would seek to realize value, if any, only through a third-party transaction.

Our Strategy

In light of our restructuring and the execution of the Merger Agreement with Scancell, the principal elements of our current strategy are:

- Complete the proposed Merger. We are working with Scancell to satisfy the closing conditions in the Merger Agreement, obtain the required stockholder and shareholder approvals, complete the SEC registration and Nasdaq listing processes, and close the related financing transactions.
- Preserve cash and maintain essential operations. We intend to limit expenditures to those required to complete the Merger, satisfy our obligations as a public company, preserve material contractual and intellectual-property rights, and maintain an orderly corporate infrastructure.
- Protect the value of partnered programs and CVR assets. We will continue to administer our agreements with Merck and the CTx CRC entities, monitor our rights under the Carina Biotech License, maintain selected intellectual property, and pursue the fiscal 2026 Australian research and development tax credit. Certain proceeds received after closing from the Merck and CTx CRC arrangements, specified intellectual property monetizations and the tax credit are expected to be payable to CVR holders, after permitted deductions, under the CVR Agreement.
- Maintain limited internal R&D activities. We maintain clinical readiness of the BNC210 PTSD program in anticipation of the completion of the Merger. If the Merger is not completed, any decision to resume, partner, sell or discontinue an asset would depend on available resources and the strategic alternatives then available.

Scientific Background

Overview of Ion Channels as a Drug Class

Ion channels facilitate the movement of charged molecules across cellular membranes and mediate electrical signaling in the CNS. Modulating ion channels can influence neurotransmission and downstream signaling in the brain. Ion channels are implicated in many diseases, but their complexity has limited successful drug discovery, and only a small portion of disease-associated ion channels have approved medicines directed to them. This biology formed the basis of our historical discovery work in neuropsychiatric and neurological disorders.

Hypercholinergic and Hypocholinergic Disease States

Our historical research focused on identifying small-molecule modulators of ion channels implicated in CNS disorders. Ion channels are membrane-spanning proteins that control the movement of ions into and out of cells and regulate neuronal excitability and signaling (Figure 1).

Alpha7 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 acetylcholine ("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 ACh levels 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 1).

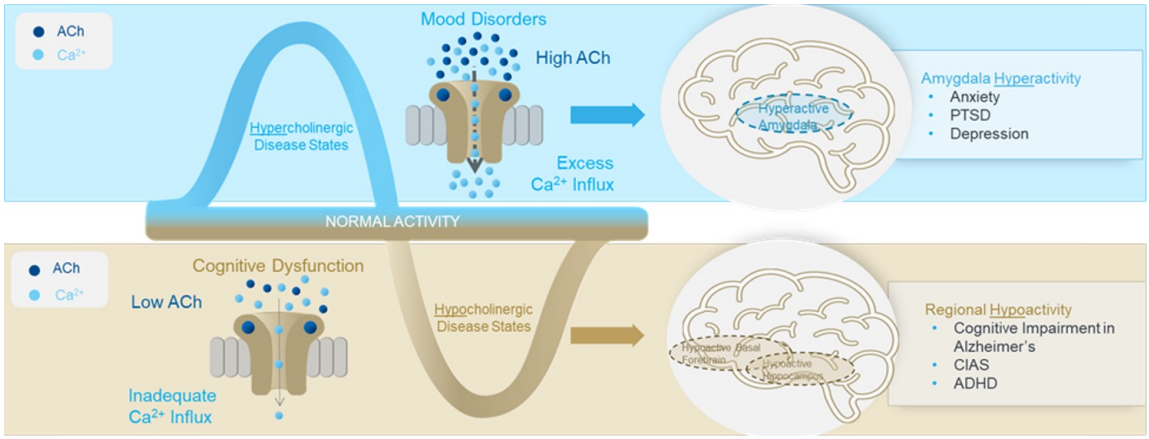

Figure 1: CNS conditions with acetylcholine imbalance at the α7 receptor.

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

Historically, our discovery and development work focused on negative and positive allosteric modulators of the alpha7 receptor for anxiety-, stress-, and cognition-related disorders. Allosteric sites on ion channels are distinct from the orthosteric site at which acetylcholine binds. Modulating an allosteric site may alter a receptor's response to naturally occurring acetylcholine without directly activating the orthosteric site.

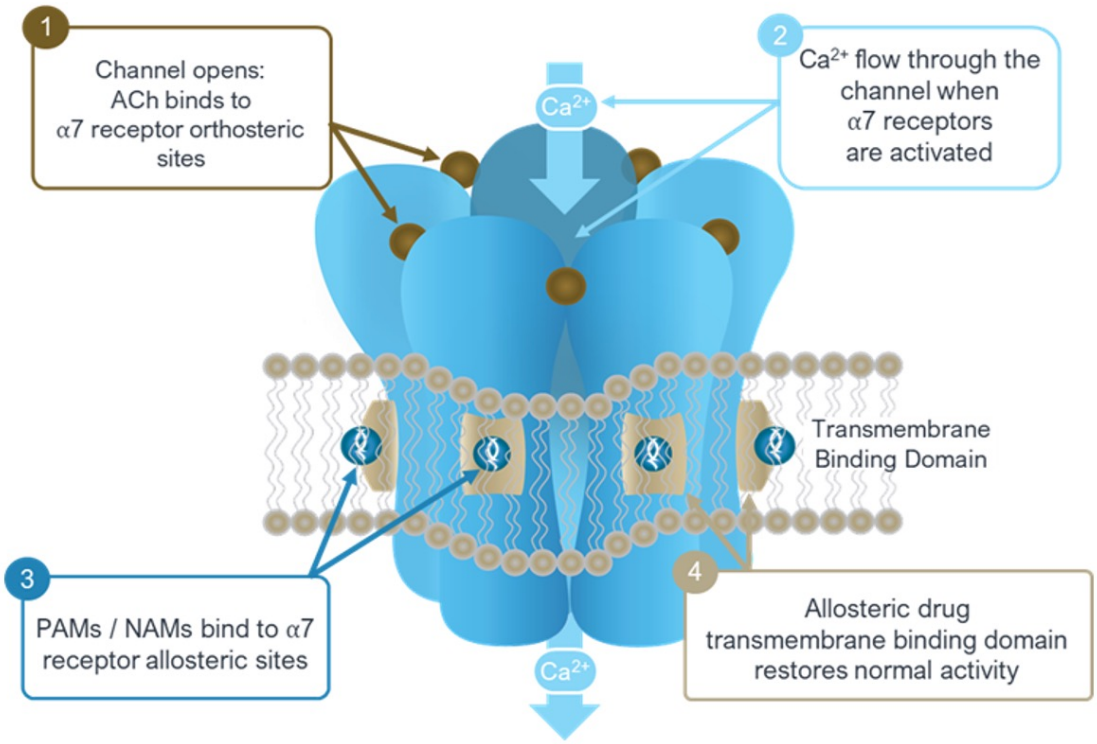

Figure 2: Structure of the α7 receptor showing the orthosteric and allosteric binding sites.

The α7 receptor has garnered significant attention as a target for cognitive deficits because of its receptor localization, the robust effects observed in preclinical studies, and the genetic implications 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, limiting their clinical utility. Allosteric modulators of the α7 receptor bind at the transmembrane region (see Figure 2) 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 dynamic interactions between molecules bound to each site, allosteric modulators "normalize" ion-channel function by mitigating hypercholinergic and hypocholinergic disease states (see Figure 2). As such, allosteric modulators offer several potential advantages, including improved safety profiles and a lower likelihood of desensitization, potentially resulting in greater efficacy than historically used orthosteric agonists or channel blockers.

We used our ion-channel biology capabilities to identify orally active, selective small-molecule alpha7 receptor allosteric modulators designed to penetrate the blood-brain barrier. This work produced BNC210 and the alpha7 PAM program, which we licensed to Merck.

Our prior clinical-development approach incorporated translational tools including electroencephalography, functional magnetic resonance imaging, behavioral paradigms, and standardized clinical scales. We used these tools to evaluate target engagement, pharmacologic activity, and clinical outcomes across the BNC210 development program.

Before the fiscal 2026 restructuring, we developed experience in regulatory interactions, clinical-trial design and execution, and manufacturing scale-up for BNC210. We no longer maintain an internal research and development organization and would need additional personnel, financing, and third-party support to resume development of any non-partnered asset.

BNC210: Clinical History and Current Status

BNC210 for Post-Traumatic Stress Disorder and Social Anxiety Disorder

BNC210 is an orally administered, selective NAM of the alpha7 receptor. It does not bind to the orthosteric acetylcholine site and, based on our preclinical work, is designed to reduce excessive receptor signaling while preserving physiological signaling. We

historically developed BNC210 for the acute treatment of SAD and the chronic treatment of PTSD. Following AFFIRM-1, we discontinued the SAD program. The PTSD program is clinic-ready, and no BNC210 clinical trial is active.

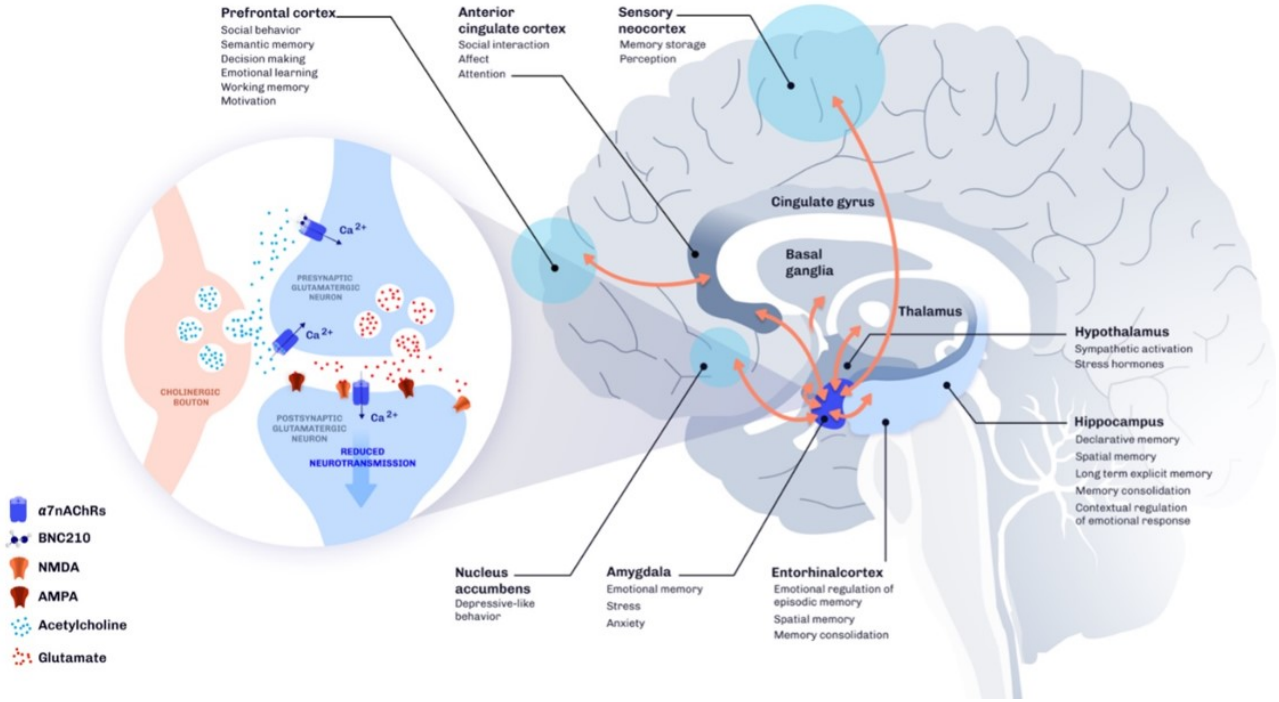

Figure 3. Action of BNC210

PREVAIL, our Phase 2 SAD trial, did not meet its prespecified primary endpoint. Post hoc analyses showed signals that informed the design of AFFIRM-1, but those analyses were exploratory. AFFIRM-1 was a randomized, double-blind, placebo-controlled Phase 3 trial in approximately 332 adults with SAD that evaluated a single 225 mg dose of BNC210 before a public-speaking challenge. AFFIRM-1 did not meet its primary endpoint, and secondary efficacy analyses did not show statistically significant differences or improvement over placebo. The safety and tolerability profile remained consistent with prior studies. We discontinued the SAD program and did not initiate AFFIRM-2.

ATTUNE, our 212-patient Phase 2b trial in PTSD, met its primary endpoint at Week 12 and showed statistically significant differences at Weeks 4 and 8. In a June 2024 End-of-Phase 2 meeting, the FDA provided feedback on a potential registrational path that contemplated one additional placebo-controlled trial and a 52-week open-label extension. The principal points discussed with the FDA included:

- the FDA agreed that CAPS-5 total symptom severity score and CGI-S could serve as the primary and key secondary efficacy endpoints, respectively, in a proposed registrational trial;
- the proposed design contemplated evaluating the 900 mg twice-daily dose used in ATTUNE and a lower dose to further characterize the balance of efficacy and safety;
- the FDA and Neuphoria reached high-level agreement on proposed participant characteristics and the methodology for determining sample size; and
- the FDA provided guidance on a proposed hepatic monitoring plan, including monitoring for excessive alcohol consumption.

We did not initiate the planned SYMPHONY Phase 2b/3 trial. The PTSD program remains clinic-ready while we pursue the Merger, and we do not expect to resume clinical trials before closing. If the proposed Merger closes, Scancell has stated that it does not intend to develop BNC210 beyond de minimis intellectual-property maintenance and enforcement activities.

Disease Background and Key Disease Drivers

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.

More than 9 million people in the United States are estimated to have PTSD. PTSD is a complex, chronic disorder with multiple symptoms and frequent comorbidities that can make it difficult to treat. Women develop PTSD at a higher rate than men after adjustment for exposure to traumatic events.

Current Treatments for PTSD and Their Limitations

There remains a significant unmet need for improved PTSD treatments. Sertraline and paroxetine are approved by the FDA for PTSD. Other antidepressants and certain anti-anxiety medicines may be used off-label. Existing therapies may have delayed onset, incomplete efficacy, tolerability limitations, or risks that lead patients to discontinue treatment.

- Antidepressants. Selective serotonin reuptake inhibitors and serotonin and norepinephrine reuptake inhibitors are commonly used as first-line pharmacotherapies for PTSD. Many patients do not achieve remission, and these medicines may require several weeks of administration before an effect is observed. Reported adverse effects may include gastrointestinal and CNS effects, sexual dysfunction, and sweating; certain antidepressants also carry a boxed warning concerning suicidality in children, adolescents, and young adults.
- Benzodiazepines. Benzodiazepines are not FDA-approved for PTSD but may be prescribed off-label. They can cause sedation and memory or motor impairment and are associated with risks of misuse, addiction, physical dependence, and withdrawal reactions.

The limitations of existing therapies support the need for PTSD treatments with improved efficacy, response rates, tolerability, and onset of action.

Potential Attributes of BNC210 for PTSD and Other Stressor-Related Disorders

In earlier acute clinical trials, BNC210 showed pharmacologic and anti-anxiety effects without evidence of benzodiazepine-like sedation, cognitive impairment, or addiction potential. These results, together with the ATTUNE findings, suggested the following potential attributes:

- 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.

Clinical Development of BNC210

BNC210 has been evaluated in 15 clinical trials involving healthy volunteers and patients with GAD, agitation, SAD and PTSD. The table below summarizes the completed studies. We are not currently conducting a BNC210 clinical trial.

The table below summarizes our completed clinical trials for BNC210:

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	3-Apr	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-Jun	Suspension and tablet; 300 mg (single dose)	Australia
1	Single Ascending Dose Safety and PK	Healthy volunteers / In-clinic	5-May	Tablet; 600 to 1200 mg (single dose)	Australia
1	Multiple Dosing Safety and PK	Healthy volunteers / In-clinic	10-Oct	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
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
3	AFFIRM-1 SAD	SAD patients / In-clinic	Approximately 332	Tablet; 225 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 the completed clinical program, the most commonly reported adverse events among participants receiving BNC210 were headache, somnolence and nausea, and most were mild. In ATTUNE, there were 14 reports of elevated liver function test results among participants receiving 900 mg twice daily. Those findings informed the hepatic monitoring plan discussed with the FDA for a potential subsequent PTSD trial. AFFIRM-1's safety and tolerability profile was consistent with prior studies. In three healthy-volunteer studies using the Addiction Research Center Inventory 49-item questionnaire ("ARCI49"), doses up to 2,000 mg per day for eight days did not show a significant signal across the 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. Subjects received 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 electroencephalographic ("EEG") activity. BNC210 had no observed effect on measures of attention, visual-motor coordination, addiction, emotion, sedation or cognition. In contrast, lorazepam impaired 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 (Figure 4). On Day -1, 24 healthy volunteers received oral nicotine doses ranging from 0.5 to 2.0 mg, after which we measured changes in alpha2 EEG-band power. Subjects then received 2,000 mg of the BNC210 liquid suspension with food for seven days and were rechallenged with nicotine on Day 7. BNC210 significantly reduced nicotine-induced alpha2-band power, which we interpreted as evidence of target engagement and negative modulation of the alpha7 receptor.

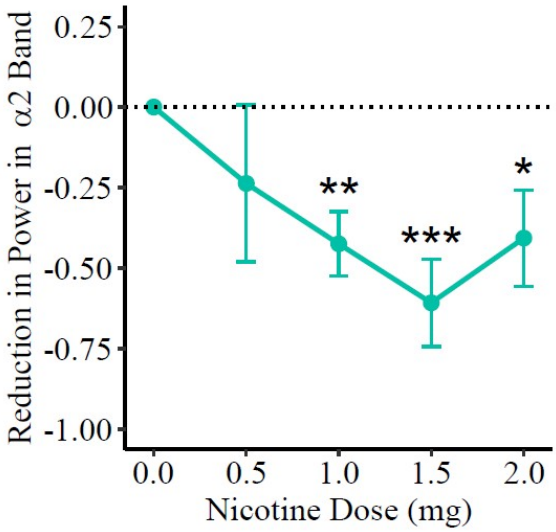

*Figure 4: BNC210 reduced nicotine-induced quantitative wake EEG responses in the power of the alpha2 band after seven days of dosing compared with predose. * p<0.05, ** p<0.01, *** p<0.001.*

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 BNC210's anti-anxiety effects. These subjects were administered cholecystokinin tetrapeptide ("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 5 (p=0.041 and p=0.048, respectively). This clinical trial also showed a trend for BNC210-treated subjects to return to baseline emotional stability more quickly than 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, and showed similar activity to benzodiazepines without the narrow dose-response common to that class of drugs.

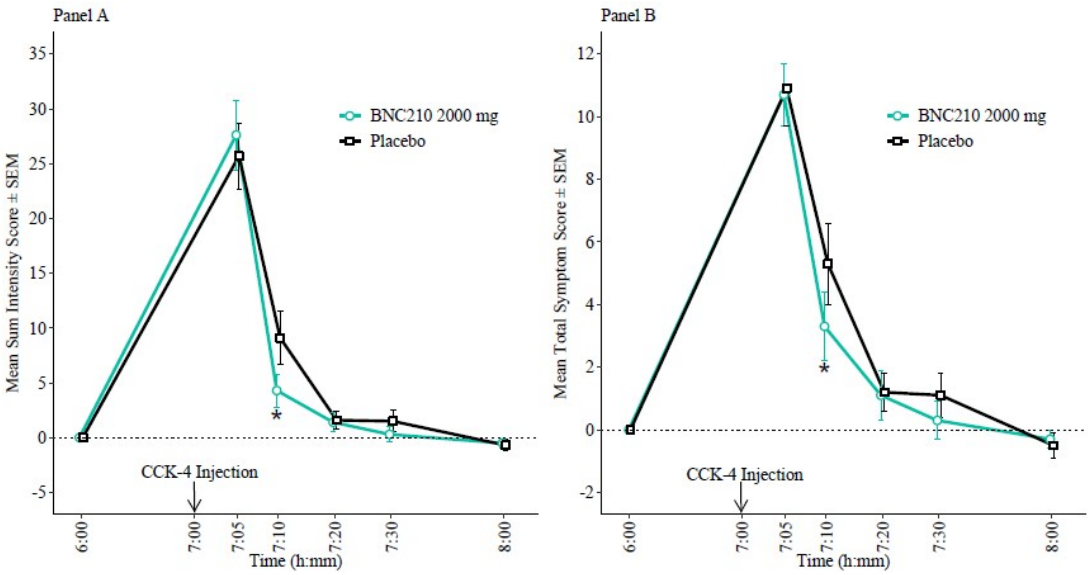

*Figure 5: Mean change from baseline for (A) Sum Intensity score (panic symptom intensity) and (B) Total Symptom score (total number of panic symptoms) on the Panic Symptom Scale. *p<0.05 vs. placebo.*

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 clinic to evaluate neural imaging responses to "fearful faces" and behavioral responses 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 magnetic resonance imaging in the resting state and changes in activation of the brain region responsible for emotional control, the amygdala, during 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 6A). 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 6B). Furthermore, in this head-to-head study, BNC210 300 mg and 2000 mg significantly reduced the intensity of defensive behavior compared with placebo, whereas lorazepam did not (BNC210 300 mg p=0.007; BNC210 2000 mg p=0.033) (Figure 6C). In addition, the 300 mg dose of BNC210 significantly reduced self-reported anxiety (p=0.003).

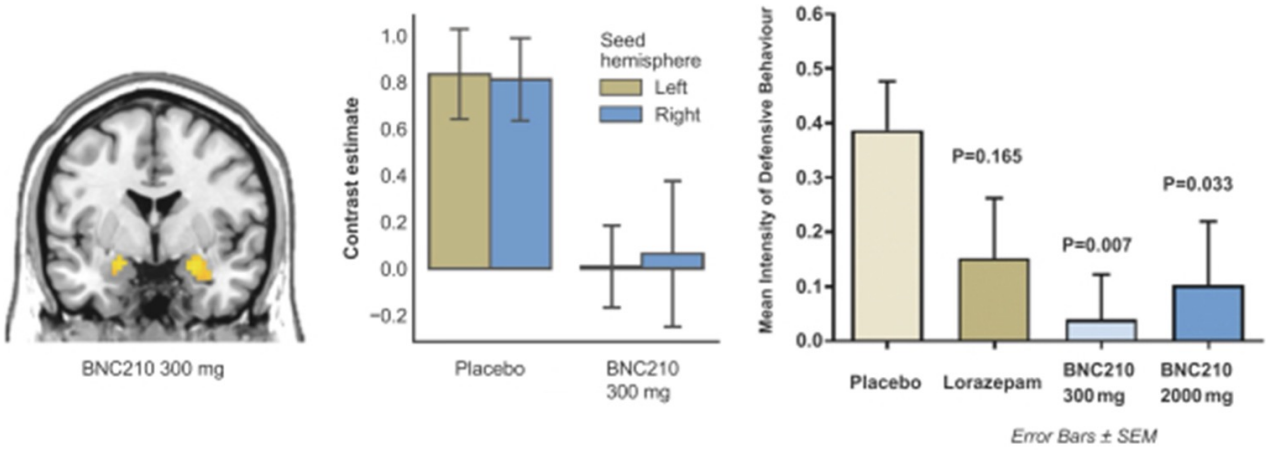

Figure 6: Phase 2 trial in GAD patients. (A) BNC210 300 mg significantly reduced activation of the left and right amygdala while viewing fearful faces; (B) BNC210 300 mg significantly reduced connectivity between the amygdala and ACC while viewing fearful faces; (C) BNC210 300 mg and 2000 mg significantly reduced threat avoidance behavior in the JORT behavioral task.

Novel, Proprietary Tablet Reformulation Effort

The earlier clinical trials discussed above used a liquid suspension formulation that required administration with a high-fat meal to provide optimal absorption. We developed a proprietary tablet formulation to reduce the food effect, improve outpatient dosing and provide more predictable pharmacokinetics. We conducted three clinical pharmacology studies of the tablet formulation, which was subsequently used in PREVAIL, ATTUNE and AFFIRM-1.

We conducted a Phase 1 crossover pharmacokinetic trial in six fasted and fed healthy subjects comparing a single 300 mg dose of the liquid suspension with the tablet formulation. The liquid suspension produced substantially lower exposure when administered fasted than when administered with food (Figure 7). By contrast, the tablet produced similar blood concentrations and exposure in fasted and fed subjects, with the expected delay in time to maximum concentration after a high-fat meal.

A separate seven-day pharmacokinetic study in ten healthy volunteers supported the 900 mg twice-daily regimen used in ATTUNE. Exposure was similar by sex, and BNC210 was generally well tolerated.

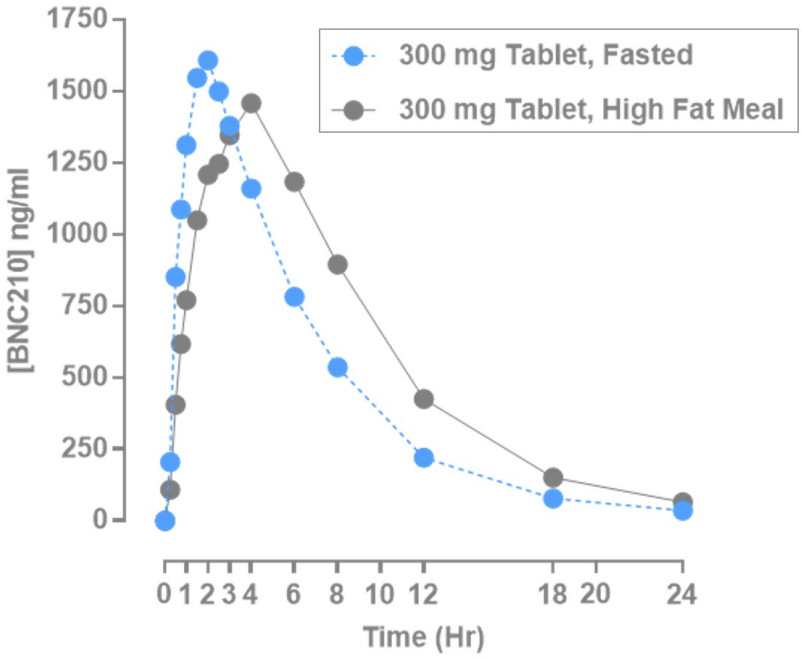

Figure 7: BNC210 tablet formulation overcomes food effect in healthy subjects.

The tablet formulation provided more predictable exposure than the earlier liquid suspension and supported evaluation of the tablet formulation of BNC210 in Phase 2 and 3 acute- and chronic-dosing studies. Across the completed clinical program, BNC210 was generally well tolerated.

BNC210 Clinical Development in PTSD

ATTUNE was a randomized, double-blind, placebo-controlled, parallel-group Phase 2b trial evaluating BNC210 monotherapy in PTSD. The trial enrolled 212 participants at 34 sites in the United States and the United Kingdom. Participants received either BNC210 900 mg twice daily or placebo for 12 weeks. The primary efficacy endpoint was change from baseline in CAPS-5 total symptom severity score at Week 12 (Figure 8).

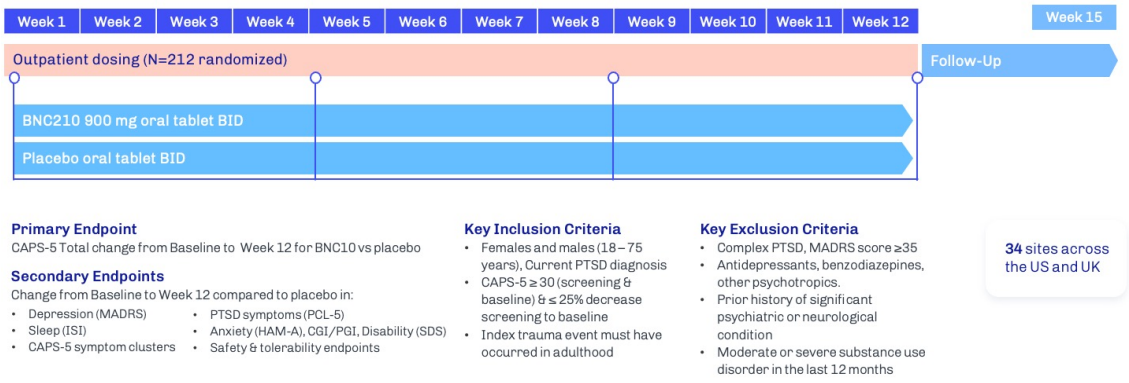

Figure 8: Phase 2b ATTUNE clinical trial design.

ATTUNE met its primary endpoint at Week 12 (p=0.048), with statistically significant differences also observed at Week 4 (p=0.016) and Week 8 (p=0.015) (Figure 9). At Week 12, BNC210 also produced statistically significant improvements in depressive symptoms

measured by MADRS (p=0.041) and sleep measured by the ISI (p=0.039) (Figure 10). Other secondary measures, including CGI-S, the Participant Global Impression-Severity scale and the Sheehan Disability Scale, showed signals or trends across visits.

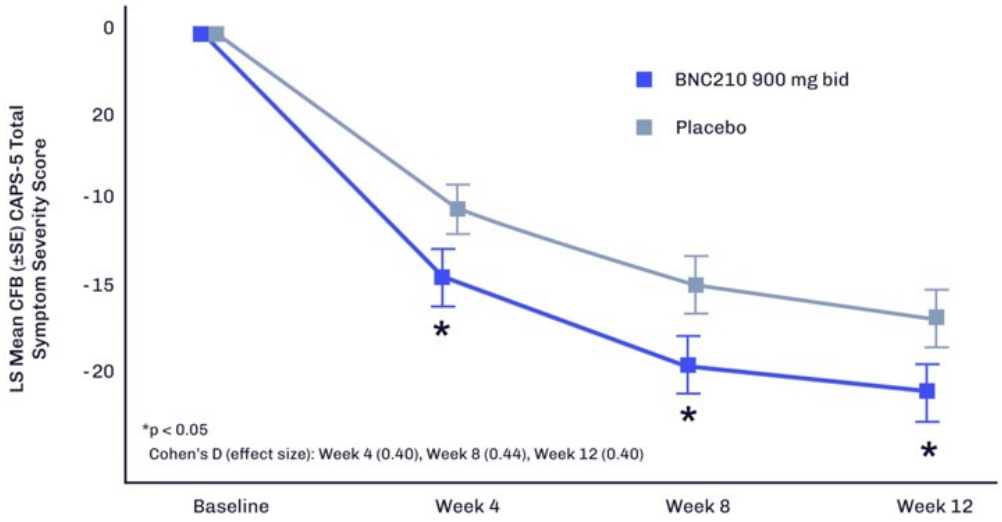

*Figure 9: ATTUNE Study – BNC210 significantly reduced change from baseline CAPS-5 total symptom severity scores in patients with PTSD. *p<0.05.*

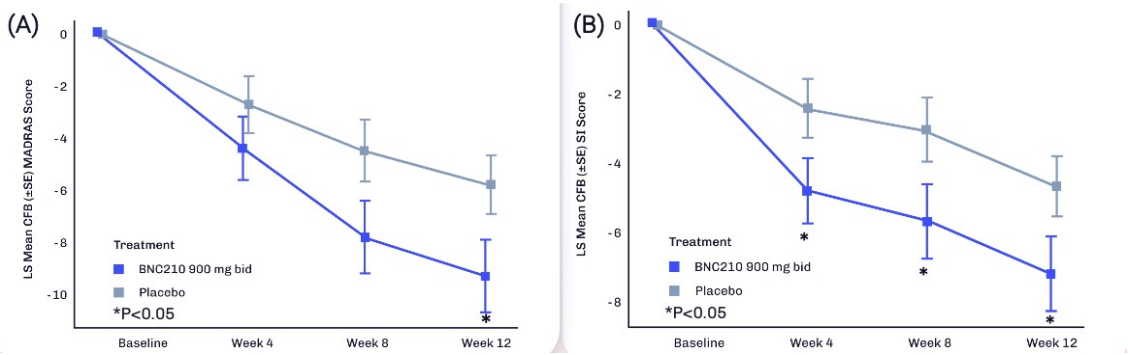

*Figure 10: ATTUNE Study – BNC210 significantly reduced change from baseline (A) MADRS depression scores, and (B) ISI scores, compared to placebo. *p<0.05*

In July 2024, we announced the outcome of an End-of-Phase 2 meeting with the FDA regarding a potential registrational path for BNC210 in PTSD. The plan discussed with the FDA contemplated one additional placebo-controlled registrational trial with a 52-week open-label extension. The principal points discussed included:

- the FDA agreed that CAPS-5 total symptom severity score and CGI-S could serve as the primary and key secondary efficacy endpoints, respectively, in a proposed registrational trial;
- the proposed design contemplated evaluating the 900 mg twice-daily dose used in ATTUNE and a lower dose to further characterize the balance of efficacy and safety;
- the FDA and Neuphoria reached high-level agreement on proposed participant characteristics and the methodology for determining sample size; and
- the FDA provided guidance on a proposed hepatic monitoring plan, including monitoring for excessive alcohol consumption.

We did not begin the contemplated Phase 2b/3 program. The PTSD program remains clinic-ready, and we are not conducting start-up or other development activities for the proposed trial.

Potential Future Development of BNC210

BNC210 has been evaluated in several anxiety and stressor-related settings, including PTSD, SAD, GAD and a human model of panic symptoms. We have no active plan to pursue additional indications. Any future development would require financing and a decision by Neuphoria or a third party to resume the program. If the Merger is completed, Scancell has stated that it does not intend to develop BNC210.

Other Programs

Alpha7 Receptor Positive Allosteric Modulator Program ("PAM") 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 because of its localization, robust preclinical effects, genetic evidence 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-response curve in preclinical assays, limiting their clinical utility.

To overcome the challenges with orthosteric agonists, we embarked on an α7 PAM discovery program that led to the identification of BNC375, a novel α7 PAM selective over related receptors that 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, to treat 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 developing 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 offer multiple advantages over orthosteric α7 receptor agonists for treating cognitive dysfunction associated with CNS diseases.

The Merck collaboration includes two clinical-stage alpha7 receptor PAM candidates. MK-4334 has completed Phase 1 safety and biomarker studies in healthy subjects. Merck initiated a Phase 2 trial of MK-1167 in December 2024 to treat symptoms of Alzheimer's disease dementia (NCT06721156). The trial was terminated in June 2026 following a planned interim analysis due to lack of efficacy. Merck controls the program's design, conduct, timing, and reporting.

Discontinued Internal Preclinical Programs

We previously maintained small-molecule discovery programs targeting several ion channels, including next-generation alpha7 receptor NAMs, Kv3.1/3.2, and Nav1.7/1.8. We stopped active work on these programs as part of the fiscal 2026 restructuring.

Our next-generation alpha7 receptor NAM work produced a patented, orally bioavailable small-molecule series that was evaluated preclinically for CNS disorders. None of these assets entered clinical development.

Our Kv3.1/3.2 program produced two patented small-molecule series that were evaluated in preclinical models of cognitive and social-function deficits. We are not advancing these or our other preclinical assets.

Legacy Oncology and Other Partnered Programs

BNC101 is a humanized monoclonal antibody directed to LGR5, a cancer stem-cell receptor expressed in several solid tumors. BNC101 completed a Phase 1 trial in colorectal cancer. In November 2020, we licensed relevant BNC101 intellectual property to Carina Biotech for CAR-T and other adoptive cell therapies. Carina's CNA3103 program is in a Phase 1/2a trial in metastatic colorectal cancer; Carina controls and funds development. Separately, through the former CTx CRC, we retain a passive economic interest in the Pfizer-controlled KAT6 program. We do not direct or fund either program.

BNC105 is a vascular-disrupting tubulin polymerization inhibitor that has been evaluated in six clinical trials. We are not actively developing BNC105 and would seek to realize value from the asset, if any, only through a third-party transaction.

Competition

The biopharmaceutical industry is highly competitive and subject to rapid technological change. Any potential future development of BNC210 or another asset would face competition from large pharmaceutical and biotechnology companies, specialty 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.

Potential competitors may have substantially greater financial, technical and human resources and more experience developing product candidates, obtaining regulatory approvals and commercializing products. These advantages could allow competitors to develop or market products more rapidly or effectively than we or any future licensee could.

If development of BNC210 is resumed, competing therapies may obtain regulatory approval sooner, demonstrate better efficacy or tolerability, or achieve broader market acceptance. Any of those outcomes could reduce or eliminate the commercial value of BNC210.

For PTSD, competition includes the following:

- Sertraline and paroxetine are FDA-approved generic antidepressants for PTSD. Other antidepressants may be recommended in treatment guidelines or prescribed off-label. Academic and industry sponsors are also evaluating pharmacologic and nonpharmacologic approaches with mechanisms different from approved selective serotonin reuptake inhibitors ("SSRIs").

Manufacturing

We do not own manufacturing facilities or employ manufacturing personnel. We relied on third-party contract manufacturers to produce BNC210 drug substance and drug product for clinical trials. No manufacturing is currently being performed for an active Neuphoria-sponsored development program. BNC210 is a small molecule manufactured through a synthetic process using commercially available starting materials. The process does not require highly specialized manufacturing equipment; however, any future clinical or commercial supply would remain subject to vendor qualification, regulatory requirements, and available financing.

Commercialization

We have not established a commercial organization or distribution capabilities. Because of the status of our internal programs and our pursuit of the Merger, we have no current plan to build a sales, marketing, or distribution organization for BNC210. Any future commercialization would require a decision to resume development, regulatory approval, substantial additional capital, and either new internal capabilities or a commercial partner.

Research Collaboration and License Agreement with Merck

In June 2014, we entered into a research collaboration and license agreement with Merck to develop alpha7 receptor PAMs targeting cognitive dysfunction associated with Alzheimer's disease and other CNS conditions. Merck controls and funds clinical development and worldwide commercialization of licensed products. The collaboration includes MK-4334, which has completed Phase 1 studies, and MK-1167, which was evaluated in a now-terminated Merck-led Phase 2 trial in Alzheimer's disease dementia following an interim efficacy analysis.

On March 19, 2025, we received a $15.0 million milestone payment triggered by Merck's initiation of the Phase 2 trial of MK-1167 (NCT06721156). Under the agreement, as amended, we may receive up to $450.0 million in additional development and commercial milestone payments associated with multiple candidates, plus royalties on net sales of licensed medicines.

Merck controls the program, and we cannot predict whether or when future milestones will be achieved or whether any licensed product will be approved or commercialized. Our information rights are limited, and we depend on Merck for updates concerning development, safety and regulatory matters.

The Merck agreement grants Merck an exclusive license in the applicable territory under specified Bionomics patent rights and know-how, with rights to sublicense, research, develop, manufacture and commercialize licensed compounds and products in the defined field.

Future milestone and royalty revenue, if any, will be recognized in accordance with applicable accounting standards when the relevant recognition criteria are satisfied.

On March 14, 2025, Merck and the Company executed the fifth amendment to the agreement. The amendment revised the patent royalty rate so that, subject to specified net-sales thresholds, royalties range from a low-single-digit percentage to a low-sub-teens percentage depending on net-sales volume.

CTx CRC and KAT6 Program

We participated in the former CTx CRC, which commercialized drug-discovery projects on behalf of its participants. Pfizer licensed a KAT6 program, which it now controls. On May 21, 2026, we received an A$1.416 million distribution after dosing the first subject in the first Phase 3 trial in ER-positive/HER2-negative metastatic breast cancer. Based on our past program contributions, we believe we may be eligible to receive approximately 4.65% of future distributions from the relevant CTx CRC entities, if any. The 4.65% represents a blended rate across two CTx CRC programs to which the Company is a participating party. We are a passive participant and cannot determine whether future milestones will be achieved, whether future distributions will be made, or the amount or timing of any distribution. Under the CVR Agreement to be entered into in connection with the Merger, certain net proceeds received after closing from the CTx CRC arrangements during the applicable period are expected to be payable to CVR holders, subject to the terms and deductions in that agreement.

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 Carina, at its request, with know-how and technical information 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 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. Carina's LGR5-targeted candidate, CNA3103, entered a Phase 1/2a trial in metastatic colorectal cancer, with patient dosing beginning in December 2023. Carina paid us an A$1.0 million milestone in October 2024. As disclosed in our Quarterly Report on Form 10-Q for the period ended March 31, 2026, we are eligible for approximately A$2.0 million of additional development and regulatory milestones if Carina advances the program to Phase 2 and A$3.0 million of additional development and regulatory milestones if Carina advances the program to Phase 3. Carina controls the timing, conduct and reporting of the program.

Carina is also obligated to pay royalties on net sales of licensed products, generally ranging from the low-single digits to the mid-single digits, subject to specified deductions, and we may receive a percentage of certain sublicensing revenue.

The Carina Biotech License expires upon the later of the expiration of all licensed patents with a valid claim covering licensed products and the 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.

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 low-to-mid-single digit royalties on the net sales of BNC210, if commercialized.

Intellectual Property

Central Nervous System

As of June 30, 2026, we owned more than 15 issued U.S. patents, one pending U.S. patent application, two pending Patent Cooperation Treaty applications, more than 30 granted foreign patents and more than 10 pending foreign patent applications in our CNS 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-traumatic 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 the U.S., Europe and Australia; and are pending in 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, 2026, 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 seek to preserve the proprietary technology that may support the value of our remaining assets, including our drug candidates and related manufacturing processes. We maintain patent protection in the United States and internationally where we believe doing so is appropriate, and we also rely on trade secrets and contractual rights.

Our ability to preserve the value of these assets depends in part on maintaining valid and enforceable patent and other proprietary rights, protecting the confidentiality of our trade secrets, and avoiding infringement of third-party rights. Following the fiscal 2026

restructuring, our intellectual-property activities are focused on maintaining and enforcing selected existing rights rather than supporting active internal research programs.

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 Investigational New Drug Application ("IND") (falling after issuance of the patent), and the submission date of an NDA, or Biologics License Application ("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. Because these adjustments and extensions require specific requirements, we cannot be assured that our patents will receive 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. Our operations are not currently subject to material seasonal influences because we have no marketed products and no active Neuphoria-sponsored development program.

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 similar in nature and scope to 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. Obtaining drug regulatory approvals and ensuring subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations requires 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 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. Preclinical studies are 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; 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 at each institution where the clinical trial will be conducted must review and approve the plan and informed consent form before the trial begins at that site and must monitor the study until completion. An IRB is charged with protecting the welfare and rights of trial participants and considers whether the risks to individuals participating in 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 are also requirements governing the reporting of ongoing 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, the FDA requires two adequate, well-controlled Phase 3 clinical trials to approve an NDA.
- Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials provide additional experience from treating 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 give the sponsor an opportunity to share data gathered to date, the FDA an opportunity to provide advice, and the sponsor an opportunity 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, manufacturers must select and test appropriate packaging and conduct stability studies 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 clinical trials and nonclinical studies performed since the last progress report must be submitted to the FDA at least annually. 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. Authorization and notification requirements also 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. Submitting an NDA requires 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, the FDA does not assess user fees 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 instead of accepting an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The FDA must also review the resubmitted application before it 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 an advisory committee's recommendations, 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 comply with cGMP requirements and are 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 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 the FDA issues a Complete Response Letter, 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 the FDA grants regulatory approval of a product, it will be granted for particular indications and may include limitations on the indicated uses for which the 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 approval if the company does not maintain 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 includes all the features of Fast Track designation, plus 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 aims to review an application within six months of filing, compared with ten months 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. No Neuphoria-sponsored development program is active. These pathways could become relevant if a program is resumed by Neuphoria or a future licensee.

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 implementation. 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 production and quality control to maintain compliance with cGMP and other regulatory requirements. 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, non-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.

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 business, which 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. Significant uncertainty remains regarding insurance coverage and reimbursement for 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 on Medicare coverage policy and payment limitations when setting their own reimbursement rates, but they also use their own methods and approval processes separate 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 time-consuming and costly and requires 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, rather than regulation, in 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 was signed into law. Among other provisions, it restored businesses' ability to immediately deduct qualifying domestic research and experimental expenditures and modified the treatment of certain orphan drugs under the Medicare drug-price negotiation provisions of the Inflation Reduction Act. The ultimate effect of these provisions on us or any future commercialization partner will depend on implementing guidance and our facts and circumstances.

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. More recently, this has led the Federal Trade Commission and the Department of Justice to investigate 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 additional state and federal healthcare reform measures to be adopted in the future, any of which could affect the amounts that federal and state governments and other third-party payors 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 part of the restructuring initiated in October 2025, we terminated all but one full-time employee and our facility leases. We currently operate with a limited workforce and rely on consultants and external service providers for executive, financial, legal, compliance and other functions. Our employee is not represented by a collective bargaining agreement.

Our current human-capital priority is to retain the personnel and external resources needed to complete the Merger, satisfy our obligations as a public company and administer our remaining contractual and intellectual-property rights.

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 discovering and developing 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 developing or advancing 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 we do not successfully develop and obtain approval for our product candidates, we may never generate any revenue. Our total accumulated deficit was $191.8 million at June 30, 2026. 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 $19.9 million as of June 30, 2026. Our operating plans and other demands on our cash resources may change because of 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. Seeking additional financing may divert our management from 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 Cancer Therapeutics Cooperative Research Centre ("CTx CRC"), 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 potential 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, 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.

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 warrant issued in the first tranche of that offering entitled the investor to purchase up to an aggregate of 1,577,706 shares of common stock, of which a Pre-Funded Warrant exercisable for 523,325 shares of common stock forming a part thereof 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, and if there were a change of control transaction, the warrant holder may be entitled to significant cash payment in lieu of exercise thereunder.

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 offering a certain number of our securities 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 1,054,381 shares of common stock (on a post-redomiciliation basis) at an exercise price of $11.88 per share, 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.

On July 20, 2026, the Company entered into a warrant amendment letter agreement with Armistice, pursuant to which the parties agreed that, if the "Black Scholes Value" (as defined in the Accompanying Warrant) otherwise payable to Armistice upon exercise of the "Cash-Out Right" (as defined in the Warrant) in connection with the proposed Scancell Merger exceeds $3,500,000, the amount of such excess (the "Excess Amount") will be payable to Armistice, at its option and in lieu of cash, in the form of Scancell ordinary shares, Scancell ADSs, warrant to purchase Scancell ordinary shares or Scancell ADSs, or a combination thereof (the "Warrant Equity Consideration"). The number of Scancell ordinary shares constituting or underlying the Warrant Equity Consideration will equal the Excess Amount (or the portion thereof paid as Warrant Equity Consideration) divided by the Scancell Per Share Price (as defined in the Merger Agreement), multiplied by 125%. Except as expressly modified by the Warrant Letter Agreement, all other terms and conditions of the Warrant remain unmodified and in full force and effect.

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 Iran and 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 materially and adversely affect our business, financial condition, 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 previously 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 general 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. Pursuant to and in response to that Notice, the Company timely submitted its plan to Nasdaq to regain compliance with the Listing Rule (the "Plan"). In response to the Company's Plan, on September 10, 2025, Nasdaq provided the Company further notice that it has accepted our Plan and granted the Company an extension of 180 calendar days from the end of the Company's fiscal year, or until December 29, 2025, to regain compliance with the Listing Rule. To that end, the Company timely filed a Proxy Statement with the SEC, together with a notice of shareholder meeting, related to the Company's 2025 annual general shareholder meeting. The Company successfully held its 2025 annual general shareholder meeting on December 12, 2025 in satisfaction of the compliance item provided in the Notice. As a result, on December 18, 2025, the Company received a further written Notice from Nasdaq's Staff stating that it has determined that the Company has regained compliance with the Listing Rule and this matter is now closed.

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 substantial time to ensuring 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. As a public company, obtaining director and officer liability insurance is significantly more expensive.

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(a) of Sarbanes-Oxley, our management is required to report upon the effectiveness of our internal control over financial reporting. This assessment must include disclosure of any material weaknesses identified by 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 common stock may decline.

We have identified a material weakness in our internal control over financial reporting. The company did not maintain effective controls over the evaluation of goodwill for impairment as of the reporting period end, specifically with respect to management's identification of potential triggering events. If we fail to successfully remediate this material weakness, or if we identify additional weaknesses in the future, we may be unable to accurately report our financial results, which could harm our business and cause our stock price to decline. While we endeavor to implement a remediation plan, we cannot assure you that any measures we take will fully remediate the deficiency in a sufficiently timely or prompt basis to prevent a future deficiency. If our remediation efforts fail, or if we uncover further deficiencies, we could face material misstatements requiring a restatement of our financial statements, lose investor confidence, experience a drop in the trading price of our Nasdaq-listed common stock, and face potential regulatory scrutiny.

Section 404(b) 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(b) 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(b) 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.

Our operating results and financial condition have been, and may continue to be, adversely affected by non-cash goodwill impairment charges.

As of June 30, 2026, we carried goodwill in the amount of approximately $3.5 million on our consolidated balance sheet. Under U.S. GAAP, we evaluate our goodwill for impairment annually, or more frequently if indicators of impairment exist. Factors such as adverse changes in macroeconomic conditions, unexpected declines in our operating performance, or a sustained decline in our stock price and market capitalization can trigger an interim evaluation. During the fiscal year, we determined that the carrying value of our reporting unit exceeded its fair value. Consequently, we recognized a non-cash goodwill impairment charge of approximately $5.4 million.

If, in future periods, Merck or other parties with whom we have licensing or development agreements were to announce additional suspension of clinical trials, research, or development involving our out-licensed assets, then we may be required to conduct additional assessment and record additional material write-downs of goodwill or other long-lived intangible assets. Any such future impairment charges could have a material adverse impact on our reported results of operations and financial condition, even though they do not directly impact our liquidity or cash flows.

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 as 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 such litigation, or any amounts paid to settle actual or threatened litigation, could require significant payments.

Our financial statements in prior years had been prepared assuming that we will continue as a going concern.

Our financial statements for the year ended June 30, 2026, were prepared assuming that we will continue as a going concern. The going concern basis of presentation assumes that we will continue in operation for a period of at least twelve months from the issuance of the financial statements in this Annual Report on Form 10-K, and will be able to realize value for our assets, discharge our liabilities and commitments in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from our inability to continue as a going concern. Our management and our board of directors are currently in the process of consummating a proposed merger transaction following the negative clinical Phase 3 trial results related to our AFFIRM-1 study in SAD. As a result, we undertook steps to reduce our operating expenses and raise additional funds to meet our working capital needs, principally through the additional sales of our securities or debt financings including, but not limited to, for the possibility of continuing our PTSD clinical trial program or other working capital needs.

However, we cannot guarantee that we will close the proposed merger and, in the alternative, obtain sufficient additional funds when needed or that such funds, if available, will be obtainable on terms satisfactory to us. If we are unable to raise sufficient additional capital or complete the proposed merger with Scancell in a timely manner, we may be unable to continue to fund our operations, develop our product candidates, or realize value from our assets and discharge our liabilities in the normal course of business. If we

cannot raise sufficient funds, or close on proposed merger with Scancell or an alternative strategic pathway, we may have to liquidate our assets and might realize significantly less than the values at which they are carried on our financial statements, and stockholders may lose all or part of their investment in our common stock. 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, period-to-period 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, 2026 and 2025, we recognized a refundable tax offset of approximately $800,000 and $300,000, 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 with a significant scientific link to Australian activities, the expenditure in Australia must exceed the expected overseas expenditure to be eligible.

If our research and development expenditures are deemed "ineligible," 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 were discontinued, or if the tax incentive rate were reduced, it would negatively affect 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, 2026 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 was relatively low through 2020, beginning in 2021 and continuing today, the economy in the United States has experienced a materially higher 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 must conduct adequate, 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 delays 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 significantly harm our business, financial condition, and prospects.

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 the Company's ability to generate revenue. To date the Company has 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 development of, obtain marketing approval for, and begin selling, 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 with respect to any commercialization of 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, potential future clinical trials may 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 available for our clinical trials at those 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 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 increase development costs for our product candidates and jeopardize our ability to obtain marketing approval to sell 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.

If our clinical trials fail to replicate results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize our product candidates.

Results from earlier preclinical studies or early-stage clinical trials of our product candidates, including positive results, may not predict the results of ongoing or future clinical trials. Furthermore, our product candidates may not be able to demonstrate similar activity or adverse event profiles as other product candidates that we believe may have similar profiles. In addition, in future clinical trials, we may utilize clinical trial designs or dosing regimens that have not been tested in prior clinical trials.

Moreover, there is a high failure rate for drugs candidate proceeding through clinical trials and there can be no assurance that any of our clinical trials will ultimately be successful. We, and many other companies in the pharmaceutical and biotechnology industries, have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier-stage development, such as the failure of our BNC210 Phase 3 clinical trial in SAD to meet its primary endpoint, and we cannot be certain that we will not face similar setbacks in the future with respect to BNC210 in PTSD.

Should we or any successor entity determine to continue the clinical trial advancement of BNC210 in PTSD, then in addition to the risk of any ongoing or planned clinical trials failing to meet primary endpoints, setbacks may also be caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials. Such failures or setbacks may have a material adverse effect on our ability to develop, obtain regulatory approval for or ultimately.

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 submitting information about the drug manufacturing process to, and having manufacturing facilities inspected 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 significantly harm our business, financial condition, and prospects.

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 were later been found to cause side effects that prevented further development.

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. 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 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 and 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, failure or delay in obtaining marketing approval in one jurisdiction may negatively affect 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 the United States, products must receive pricing and reimbursement approval before they can be commercialized. Obtaining this approval can substantially delay 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 43 days beginning on October 1, 2025, 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 FDA or an applicable foreign regulatory authority may accept study data from clinical trials conducted outside the United States or another jurisdiction, 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 to focus on clinical programs and product candidates indications that leverage 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 have historically been highly dependent on the members of our senior management and scientific staff. We may in the future have difficulties in attracting and retaining key personnel, and if we fail to do so our business may suffer.

We have historically been highly dependent on the members of our senior management and scientific staff 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 for existing and/or future clinical programs and assets. 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 sabotage, systems change frequently and are often not recognized until they are 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 fiscal 2025, we became aware of a breach of our email system, which we quickly remediated. 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.

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 we complete our clinical trials, 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 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 relatively recent 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 for 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 significantly harm our business, financial condition, results of operations, and prospects. 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. Our ability 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 we establish any such collaborations in the future, we may have limited control over the amount and timing of resources our collaborators dedicate to developing 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 on 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 to execute 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 may continue to design the preclinical studies and clinical trials for our current or future product candidates, if any, 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 and 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 and adversely affect third parties' willingness or ability to conduct our clinical trials and may subject us to unexpected cost increases 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 time in the past, they may subordinate our needs in the future to those of 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 can find a replacement supplier, that 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.

Assuming we do not consummate a strategic transaction that results in a change of control, or if any successor entity determines to develop existing or future Company clinical assets, 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 may 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 clinical trial ready 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 currently rely, and expect to continue to rely, on third parties to manufacture 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, production costs and yields, quality control (including lot consistency, product stability, and product testing), operator error and availability of qualified personnel, and 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 toward potential approval and commercialization, we expect various aspects of the manufacturing process to be altered 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 materially and adversely affect 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 a product's effectiveness 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 unmeritorious 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 on awareness of and acceptance of our current or future product candidates within 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. 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 of any current or future product candidates, 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 incurred these commercialization expenses prematurely or unnecessarily. 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 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 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 Veterans 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 affect 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.

Significant uncertainty remains regarding insurance coverage and reimbursement for 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 what third-party payors will decide regarding 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 we cannot assure that we will be able to maintain such insurance or that the amount 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 common stock.

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, and 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 require 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 clinical trial results, 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 them. In such a 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. Phase 3 clinical trials are lengthy and, for 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. 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, if undertaken. 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 adversely affect 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, failure to obtain approval in one jurisdiction may negatively affect 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. Ambiguities remain about 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, other providers, or entities with whom we expect to do business are found not to be 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 ACA's constitutionality. 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; however, significant legislative, executive, and regulatory changes have occurred since 2021, including the expiration of enhanced marketplace premium tax credits, new administrative rules on enrollment verification, and ongoing federal court battles over marketplace operations.

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 beneficial 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 increasingly use bidding procedures to determine which pharmaceutical products and 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, require us to accept 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. For example, 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 inconsistently from one jurisdiction to another, and

may conflict with one another or with 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 largely 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 strong intellectual property protection for those products, as they 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 that 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, 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 could put 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 about our ability to obtain patents in the future, this combination of events has created uncertainty about 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, 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 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 the patent examiner and we 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 patents or violating others' proprietary rights. 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 that case, we could ultimately be forced to cease using those 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. Failure to name the proper inventors on a patent application can result in the patents issued 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 successfully defend against such claims, litigation could result in substantial costs and distract 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 trade secret theft, 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 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 successfully defend 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 rights to these trademarks and trade names, or we may be forced to stop using them, 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.

Risks Relating to the Consummation of the Proposed Merger and such transactions related thereto

We may not be successful in consummating a strategic transaction, any strategic transaction will require us to devote significant time and cost away from potential operational plans and a strategic transaction that we may consummate could have negative consequences.

In October 2025, we announced that our AFFIRM-1 Phase 3 trial of BNC210 for the acute treatment of social anxiety disorder ("SAD") did not meet its primary or secondary endpoint of change from baseline to the average of the performance phase of the public speaking challenge in Subjective Units of Distress Scale (SUDS) scores. Therefore, our management and board of directors determined that we would discontinue all clinical development of BNC210 in SAD, and assess plans relating to work on BNC210 in PTSD. Simultaneously, our board of directors has determined to commence a robust review of strategic alternatives to advance its promising pipeline programs and maximize stockholder value. Strategic alternatives under consideration included, but were not limited to, mergers, acquisitions, partnerships, joint ventures, licensing arrangements or other strategic transactions. In addition, on December 2, 2025, Lynx1 Master Fund LP ("Lynx1") revised its previous non-binding proposal to acquire all outstanding shares of the Company for $4.75 per share in cash. This revised offer followed a previous higher non-binding proposal of $5.20 per share made on November 10, 2025, which Lynx1 withdrew on November 18, 2025. The November 10, 2025 indication of interest from Lynx1 included its intent to nominate certain individuals to stand for election to Neuphoria's board of directors at the Company's 2025 Annual Meeting of Stockholders ("Annual Meeting"), which was held on December 12, 2025. In relevant part, at the Annual Meeting a quorum to properly hold the meeting was met, and the stockholders voted in favor of the election of the Company's existing Class 1

directors, Peter Miles Davies and David Wilson, by roughly a vote of 84% to 16%. The complete results of that annual stockholder meeting can be found in the Company current report on Form 8-K filed by the Company with the SEC on December 17, 2025. As previously disclosed, Neuphoria's board of directors determined that the revised bid by Lynx1 was undervalued, provided no meaningful premium to stockholders, and further determined to continue with its ongoing strategic alternatives review process.

Following our announcement in July 2026 of the execution of an agreement and plan of merger with Scancell, we expect to continue to devote substantial time and resources to consummating the proposed merger; however, there can be no assurance that proposed merger will be successfully completed, completed in a timely manner, or that it will lead to increased shareholder value.

We may also incur additional unanticipated expenses in connection with this process, including but not limited to contract terminations, buyouts, damages resulting therefrom, costs and/or damages arising from change of control triggers, and other similar items that may cost more than anticipated or which may be reasonably unanticipated at this time. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or a transaction is completed. Any such expenses will decrease the remaining cash available for future use in our business, prospects or other asset development or acquisition.

Further, should we determine to fully resume the development of BNC210 in PTSD, the development and any potential commercialization of BNC210 for this indication will require substantial additional cash to fund the costs associated with conducting the necessary clinical testing and obtaining regulatory approval. Consequently, assuming the consummation of the proposed Scancell merger, it may choose not to spend additional resources and continue development of BNC210 or any of our other product candidates and may attribute little or no value, in such a transaction, to those product candidates.

In addition, any strategic business combination or other transactions that we may consummate in the future could have a variety of negative consequences, and we may implement a course of action or consummate a transaction that yields unexpected results that adversely affect our business and decrease the remaining cash available for use in our business.

If we are not successful in consummating the proposed Scancell merger, or we do not complete it in a timely fashion, this may cause reputational harm with our shareholders and the value of our common stock shares may be adversely impacted.

Even if we successfully consummate a transaction from our strategic evaluation, we may fail to realize all of the anticipated benefits of the transaction, those benefits may take longer to realize than expected, or we may encounter integration difficulties.

Our ability to realize the anticipated benefits of any potential business combination or any other result from our pursuit of strategic alternatives are highly uncertain. Any anticipated benefits will depend on a number of factors, including our ability to realize what is believed to be higher value of certain assets due to contractual restrictions and limitations, the ability to integrate with any future business partner and our ability to generate future shareholder value. The process may be disruptive to our business and the expected benefits may not be achieved within the anticipated time frame, or at all. The failure to meet the challenges involved and to realize the anticipated benefits of any potential transaction could adversely affect our business and financial condition.

Any executed strategic transaction may not maximize or even enhance stockholder value, could result in total costs and expenses that are greater than expected, and could make it more difficult to attract and retain qualified personnel, each of which could have a material adverse effect on our business. In addition, a potential strategic alternative may require stockholder approval and stockholder approval may not be obtained (including if any significant or activist shareholder may not vote for such transaction or it/they may attempt to actively work against the approval of such strategic or other transaction) and, therefore, we may not successfully consummate the strategic alternative.

In addition, the market price of our common stock may reflect a market assumption that a strategic alternative will occur, and a failure to complete a strategic alternative could result in negative investor perceptions and could cause a decline in the market price of our common stock, which could adversely affect our ability to access the equity and financial markets, as well as our ability to explore and enter into different strategic alternatives.

If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.

Although there can be no assurance that a consummation of the proposed merger with Scancell will result from the process we have undertaken, the negotiation and consummation of the Merger Agreement and related transactions will require significant time on the part of our management and members of our Board of Directors, and the diversion of their attention may further disrupt our business.

The consummation of the proposed Scancell merger or any other such transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including, but not limited to:

- increased near-term and long-term expenditures;
- exposure to unknown liabilities;
- higher than expected acquisition, disposition or integration costs;
- write-downs of assets or goodwill or incurrence of non-recurring, impairment or other charges;

- increased amortization expenses;
- difficulty and cost in combining the operations of any acquired business with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;
- inability to retain key employees of our company or any acquired business;
- termination of existing agreements that may lead to the loss of certain valuable assets, for little or no value;
- potential exchange or buyout costs related to certain existing agreements being much higher than reasonably anticipated;
- additional activist investor actions that may involve additional time and capital resources to resolve; and
- possibility of future litigation.

Any of the foregoing risks could have a material adverse effect on our business, financial condition and prospects.

If a strategic transaction is not consummated, our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our shareholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that a strategic transaction will be completed. If a strategic transaction is not completed, our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our shareholders will depend heavily on the timing of such decision and, with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our board of directors were to approve and recommend, and our shareholders were to approve, a dissolution and liquidation, we would be required under Delaware law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our shareholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. The amount of cash available for distribution to our stockholders will depend heavily on the timing of such dissolution and liquidation, and the amount of cash that will need to be reserved for commitments and contingent liabilities. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If we pursued dissolution and liquidation, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock shares could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up.

Our ability to consummate a strategic transaction depends on our ability to retain key executives required to consummate such transaction, as well as resolving the continuation, amendment or termination of certain contracts involving key assets of the Company.

Our ability to consummate the proposed Scancell merger or another strategic transaction depends on our ability to retain key executives required to consummate such a transaction, the loss of whose services may adversely impact our ability to consummate such transaction. In connection with the evaluation of strategic alternatives and in order to extend our resources, we implemented a reduction in our workforce which was completed, whereby the Company terminated all but one full time employee, and also terminated its facility leases, and cancelled and/or suspended all research and development activities while it sought to identify a partner with which to execute a strategic merger for the benefit of existing shareholders of Neuphoria. The strategic review process is supported by our experience at the board of directors, executive management, and remaining support staff, as well as by the retention of outside advisors and consultants. To this end, the Company's board of directors terminated the employment agreement of our CEO, Dr. Spyridon Papapetropoulos, M.D, effective December 31, 2025, at which time Dr. Papapetropoulos ceased to serve as the full-time President and CEO of the Company. Pursuant to the terms of this employment agreement, Dr. Papapetropoulos was entitled to severance payment in an aggregate amount equal to his annual base salary, target bonus amount, and medical insurance premiums, 50% of which was paid in calendar year 2025, and the balance of such severance to be paid in partial installments in calendar year 2026 until paid in full.

Simultaneously and in connection with the termination of the foregoing employment agreement, Dr. Papapetropoulos entered into a consulting agreement with the Company (the "Consulting Agreement") effective January 1, 2026, under which Dr. Papapetropoulos will serve as the interim CEO to the Company for up to twelve months to support the execution of the Company's contemplated strategic transaction and ensure a seamless transition. Under the terms of the Consulting Agreement, Dr. Papapetropoulos will receive consulting fees equal to $800 per hour for services up to approximately 40 hours per month for his continued services, which aggregate hours shall not exceed more than twenty percent of the total hours performed while acting as the full-time CEO of the Company.

Our ability to successfully complete a strategic transaction depends in large part on our ability to retain certain of our remaining key personnel; if we fail to retain them, we risk disruption to our consummation of a strategic alternative as well as business operations.

In addition, strategic mergers and similar transaction structures often require restructuring material contracts to realize synergies or comply with the new corporate structure. If, for example, certain collaborative or development partners of the Company do not agree to an assignment, consent or such other seamless continuation of such contract in connection with a successor entity, or in the alternative, a reasonable amendment, if necessary, to such contracts, the merger or other strategic transaction's economic rationale may fail, and a transaction may not be consummated.

Failure to complete the proposed Scancell Merger and such transactions related thereto could negatively impact the Company.

If the proposed merger with Scancell and related transactions are not completed for any reason, there may be adverse consequences, and the Company may face negative reactions from the financial markets, as well as from its investors, employees, or other stakeholders. For example, the Company's business may have been adversely impacted by the failure to pursue other beneficial opportunities due to management's and the Board's focus on the proposed Merger and such other transactions related thereto, without realizing any of the anticipated benefits of completing the proposed Merger. Additionally, the market price of the Company's Common Stock could decline to the extent that current market prices reflect a market assumption that the proposed Merger and such other transactions related thereto will be completed. The Company could also be subject to litigation related to the failure to consummate the proposed Merger and such other transactions related thereto or to proceedings commenced against the Company to perform its obligations pursuant to the Merger Agreement.

Additionally, the Company has incurred and may continue to incur substantial expenses in connection with the negotiation and completion of the transactions contemplated by the Merger Agreement, as well as the costs and expenses of preparing, filing, printing, and mailing any necessary joint proxy statement/prospectus, and all filing and other fees paid in connection with the proposed Merger and such other transactions related thereto. If the proposed Merger and such other transactions related thereto are not consummated, the Company would have paid these expenses without realizing the expected benefits of the proposed Merger and such other transactions related thereto.

In the past, litigation has often followed certain significant business transactions, such as the sale of a company, announcement of a strategic transaction, or the announcement of negative events, such as negative results from additional clinical trials. These events may also result in investigations by the Securities and Exchange Commission (the "SEC"). We may be exposed to such litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management's attention and resources, which could adversely affect our cash resources and our ability to consummate a potential strategic transaction, and our insurance coverage may not be sufficient to cover the entire cost of such matters.

The Company may not be able to satisfy the requirements for the closing under the Merger Agreement, which may cause material adverse consequences due to the consequent failure to complete the proposed Merger and such other transactions related thereto.

Consummation of the proposed Merger is subject to certain closing conditions, including, among others, (i) the Company Stockholder Approval and the Scancell Shareholder Approval; (ii) approval of the Nasdaq listing of the Scancell ADSs (and the Scancell Ordinary Shares represented thereby); (iii) Subscription Agreements remaining in full force and effect and Scancell receiving not less than $75.0 million in gross cash proceeds from the concurrent financing prior to or substantially simultaneously with the closing; (iv) effectiveness of the Form F-4; (v) circulation of the Scancell Circular to Scancell's shareholders; (vi) Closing Net Cash of at least $10,000,000 as of December 31, 2026 or at the Closing, whichever occurs earlier; (vii) receipt by Scancell of certain required third-party consents; and (viii) execution and delivery by the applicable signatories of the Company Lock-Up Agreements and the Scancell Lock-Up Agreements, each of which shall be in full force and effect as of immediately following the Effective Time. The failure to meet the material conditions requisite to the closing of the proposed Merger may prevent the consummation of the Merger, and the consequent negative effects of such failure to meet these conditions and successfully close the transaction related thereto.

The Merger Agreement also contains certain termination rights for the Company and Scancell, including termination by mutual written agreement, by either party if the Merger has not been consummated by February 28, 2027, subject to a 60-day extension if the SEC has not declared the Form F-4 effective, by either party if a final and non-appealable governmental order permanently enjoins or prohibits the Merger, by either party if the Company stockholder approval or Scancell Shareholder Approval is not obtained, by Scancell in certain circumstances involving a Company adverse recommendation change or material breach of the Company's no-solicitation obligations, and by either party for certain uncured breaches by the other party.

If the Merger Agreement is terminated due to the failure to obtain the Company Stockholder Approval at the Company Stockholder Meeting, the Company may be required to pay to Scancell a Company No Vote Payment, equal to Scancell's aggregate fees and expenses reasonably incurred in connection with the transactions contemplated by the Merger Agreement. Similarly, if the Merger Agreement is terminated due to the failure to obtain the Scancell Shareholder Approval at the Scancell Shareholder Meeting, Scancell

may be required to pay to the Company a Scancell No Vote Payment, equal to the Company's aggregate fees and expenses reasonably incurred in connection with the transactions contemplated by the Merger Agreement.

The Company and Scancell will incur substantial costs related to the proposed Merger and integration of their businesses.

The Company and Scancell have incurred and expect to incur a number of non-recurring costs in furtherance of the consummation of the proposed Merger and transactions related thereto, including legal, financial advisory, accounting, consulting, and other advisory fees; regulatory filing fees; financial printing and other transaction-related costs. Some of these costs are payable by either the Company or Scancell whether the proposed Merger or the transactions related thereto are completed or not. These costs may stem from the complex integration of a non-domestic company, numerous processes, policies, operations, technologies, and systems across areas such as purchasing, accounting, finance, payroll, compliance, treasury and vendor management, risk management, business operations, pricing, and employee benefits.

While the Company and Scancell estimate a certain level of integration costs, many factors beyond their control could increase the total amount and timing of these expenses. Additionally, many of these costs are inherently difficult to estimate with precision. As a result, assuming that the proposed Merger and related transactions are consummated, the combined company may need to take certain accounting and financial charges following the proposed Merger's consummation, and the amount and timing of such charges are uncertain. Moreover, the Merger consummation and integration efforts may divert management's attention and resources, further impacting the combined company's performance both during and after the integration period.

The Proposed Merger transaction is subject to review, clearance and approval of both the Securities and Exchange Commission, as well as the Nasdaq Stock Market.

The completion of the Company's proposed Merger transaction with Scancell is subject to the receipt of necessary consents, clearance, and/or review by the SEC and approval of our application for listing on the Nasdaq Stock Market. We cannot assure you that the SEC will timely clear the Company's filings, including the Registration Statement on Form F-4 relating to the Merger, or at all, including the financial statements related thereto and incorporated therein, or that Nasdaq will approve our listing application on a timely basis, or at all.

Upon the consummation of the proposed Merger, existing holders of the Company's Common Stock will experience substantial dilution of their ownership interest in the Company, which could materially reduce or be perceived to reduce the value of their Company shareholdings.

Assuming that the proposed Merger closing occurs, the Company will issue the shares of its Common Stock at the Exchange Ratio pursuant to the terms of the Merger Agreement, which is calculated therein as follows: upon the closing, on a pro forma basis and based upon the number of Scancell ADSs expected to be issued in connection with the Merger and the PIPE Financing. Pre-Merger stockholders of the Company (other than Subscribers in the Scancell private placement financing) are expected to own approximately 11.1% of the combined company, pre-Merger shareholders of Scancell will own approximately 64.9% of the combined company and the Subscribers in the Scancell private placement financing are expected to hold approximately 17.3% (assuming gross proceeds from the PIPE Financing of $38.6 million), in each case calculated on a fully diluted basis, using the treasury stock method, and subject to certain assumptions, including (i) the Scancell Valuation of $144,612,002, (ii) the Company Valuation of $24,598,949, and (iii) the relative capitalization of Scancell and the Company, as determined in accordance with the Exchange Ratio formula set forth in the Merger Agreement. The approximately 7.0% remainder of the equity is anticipated to be distributed across either or both a of (i) an equity raise of approximately $12.0 million (approximately £9.0 million) targeting UK or other European institutional investors; and (ii) a retail offering of up to $3.0 million (approximately £2.3 million) made available via the Winterflood Retail Access Platform to existing shareholders and UK retail investors.

Additionally, if the Company successfully registers the resale of any restricted shares of the Company's Common Stock related to outstanding warrant or other shares issuable in connection with any future financing, a substantial number of additional shares may become freely tradable. The presence of these newly registered or tradeable shares, as well as the perception that they may be sold, could create an "overhang" in the market. Specifically, if the trading volume of the Company's Common Stock cannot absorb the sales of these newly registered or tradeable shares, the price per share may decline.

The future results of the combined company following the consummation of the proposed Merger and such related transactions may suffer if it does not efficiently manage the various regulatory and accounting compliance issues of the newly combined company.

Assuming that the consummation of the proposed Merger and such related transactions occur, the combined company's future success will depend, in part, on its ability to manage these expanded operations, which may pose challenges for management, including challenges related to oversight of new operations and the associated increase in capital financing needs, expenditures and complexity. The combined company may also face heightened scrutiny from governmental and regulatory authorities as a result of its expanded

scale, U.S. compliance issues involving the Nasdaq Stock Market and the SEC. There can be no assurance that the combined company will be successful or that it will realize the operating efficiencies or other benefits currently anticipated from the consummation of the Merger and such related transactions.

The anticipated pro formas of the combined consolidated financial information of the Company and Scancell will be preliminary and the actual consideration to be issued in the proposed Merger and such related transactions, as well as the actual financial condition and results of operations of the combined company after the proposed Merger, may differ materially.

The anticipated pro formas of the combined consolidated financial information of the Company and Scancell are currently preliminary and indicative and may not necessarily and ultimately prove to be what the combined company's actual financial conditions or results of operations will be in the future. The pro forma combined consolidated financial information will reflect potential adjustments, which are based upon preliminary estimates. Among other things, the actual value of the consideration that the Company receives upon the consummation of the proposed Merger, assuming that it occurs, may vary significantly from the value used in preparing the unaudited pro forma combined consolidated financial information provided in tandem with these risk factors and the SEC filings of which they form a part. Accordingly, any final acquisition accounting adjustments may differ materially from the pro formas and any adjustments which may be reflected in the pro formas combined consolidated financial information.

Scancell's directors, executive officers and principal stockholders will have substantial control over the Company after the consummation of the proposed Merger, which could limit other stockholders' ability to influence the outcome of corporate matters and key transactions, including a change of control.

Upon (and assuming) the consummation of the proposed Merger, the Company's executive officers, directors and existing shareholders will own a significant minority of the outstanding shares of the Company Common Stock (Ordinary Shares of the successor company), after giving effect to the Exchange Ratio related to the proposed Merger. This significant concentration of ownership may have a negative impact on the trading price of the Company's common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. In addition, these stockholders will be able to exercise a significant level of control over all matters requiring stockholder approval, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may also have interests that differ from other stockholders of the Company and may vote in a way with which other stockholders of the Company disagree, and which may be adverse to the Company's interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of the Company, could deprive the Company's stockholders of an opportunity to receive a premium for their common stock as part of a sale of the Company and might ultimately affect the market price of the Company Common Stock.

The market price of the Company's Common Stock may be affected by factors different from those currently affecting the shares of the Company's Common Stock assuming the consummation of the proposed Merger and such related transactions.

The Company's business differs from that of Scancell, and certain significant adjustments will be made to the Company's operations assuming the consummation of the proposed Merger and such related transactions occur. Accordingly, the results of operations of the combined company and the market price of the Company's common stock after the assumed consummation of the proposed Merger and such related transactions may be affected by factors different from those currently affecting the independent results of operations of the Company.

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 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 Interim 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

The lease for our offices located at 200 Greenhill Road, Eastwood, South Australia 5063, Australia, expired on May 31, 2026. We have no remaining leased properties at June 30, 2026.

Item 3. Legal Proceedings.

Our management is not aware of any current formal material 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 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, 2026, there were 3,348 holders on record of our common stock. This number is not representative of the number of beneficial holders of our common stock nor are they representative of where such beneficial holders reside, as many of these shares of 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, 2026, 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.

As part of our ongoing strategic review of our operations and portfolio, we are assessing plans for our lead product candidate, BNC210, an oral, proprietary, selective NAM of the α7 receptor, for the chronic treatment of Post-Traumatic Stress Disorder ("PTSD"), which program we have paused to allow for a broader assessment in light of potential strategic transactions, structure and timing.

There remains a significant unmet medical need for the over 9 million patients in the United States alone suffering from 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. 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, 2026, our operations have been financed primarily by aggregate net proceeds of $211.0 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 (the "Merck Agreement"), and $67.9 million from Australian research and development credits and government grants and assistance.

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.

Since inception, we have incurred significant operating losses. As of June 30, 2026, the Company had working capital of $20.3 million, an accumulated deficit of $191.8 million, and cash and cash equivalents of $19.9 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.

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 net losses of $13.5 million and $0.4 million for the twelve months ended June 30, 2026 and 2025, respectively. The Company also used $12.4 million of cash in operating activities during the twelve months ended June 30, 2026.

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.

Based upon the Company's current operating plans, reflective of recent cost curtailments, the Company believes that its existing cash and cash equivalents will be sufficient to continue funding its operating activities beyond the second quarter of fiscal year 2028, 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.

Licenses and Collaborations

The Company became a multi-party participant in the Australian Government-supported Cancer Therapeutics Cooperative Research Centre ("CTx CRC" or "CRC") in 2007. The CRC collaborative arrangement was established to support oncology research, development, and commercialization activities. Approximately seventeen participants contributed cash, personnel, intellectual property, and in-kind resources during the initial phases of CRC's existence. The Company holds an approximate 4.65% participation interest in CRC.

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. Under the agreement, as amended, Neuphoria is eligible to receive up to an aggregate of $450 million in milestone payments comprised of $275 million for the achievement of certain development milestones and $175 million in potential commercial milestones, plus royalties on net sales of any licensed medicines.

On March 14, 2025, the Company and Merck executed the Fifth Amendment to the Merck 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, 2026.

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 A$2.0 million and A$3.0 million in certain development and regulatory milestone payments if Carina advances the development of the therapy to a Phase 2 or Phase 3 trial, respectively. 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) during the twelve months ended June 30, 2025, included in this Form 10-K.

Components of Operating Results from Continuing Operations

Revenue

The Company evaluates arrangements to determine whether they meet the definition and scope of a collaborative arrangement. Arrangements within the scope of ASC 808 may include components subject to other authoritative accounting guidance, including ASC 606. Transactions with a counterparty that is a customer, in the context of a distinct good or service, are accounted for in accordance with Topic 606. Transactions that are not within the scope of Topic 606 are accounted for in accordance with other applicable authoritative accounting guidance, as appropriate.

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, 2026 and 2025 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 PTSD, if reinstated.
- 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 achieve regulatory approval for any of our product candidates. We may obtain unexpected results from our preclinical studies and clinical trials, if reinstated. We may elect to discontinue or modify paused 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 have historically accounted for a significant portion of our operating expenses. Assuming we do not consummate the proposed Merger, or if we do consummate the proposed Merger and our successor continues to conduct research and development activities, we expect our future research and development expenses to increase substantially, including if our paused programs are reinstated. We do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization for any of our paused programs. Numerous factors affect the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined accurately 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

Assuming we do not consummate the proposed Merger, or if we do consummate the proposed Merger and our successor continues to conduct research and development activities, we expect our general and administration expenses to increase over the next several years to support research and development activities if our programs are reinstated, in addition to operating as a publicly reporting 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 legal fees, and insurance.

Restructuring Costs

In October 2025, management committed to a plan to discontinue or pause, in regards to BNC210 in SAD and PTSD, its research and development activities while it sought to identify a partner with which to execute a strategic merger and/or such other transaction(s), if any, for the benefit of existing shareholders of Neuphoria. As part of the restructuring initiative, the Company terminated its facility leases, wrote off the remaining carrying value of the right-of-use asset, derecognized the associated operating lease liability, and terminated substantially all of its employees. A liability equivalent to the derecognized lease liability has been included in Accrued restructuring expenses (see Notes 6 and 9 to the consolidated financial statements). The write-offs are included in restructuring costs in the consolidated statements of operations and other comprehensive income (loss) for the twelve months ended June 30, 2026.

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, 2026 and 2025, 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, 2026 and 2025. See "Quantitative and Qualitative Disclosures About Market Risk" for more information.

Results of Operations

Comparison of Fiscal Years ended June 30, 2026 and 2025

	Year Ended June 30,		Increase (Decrease)	
	2026	2025	Amount	Percent
Revenue	$ 1,174,165	$ 15,649,448	$ (14,475,283)	(92.5)%
Research and development	(3,545,421)	(9,005,097)	(5,459,676)	(60.6)%
General and administrative	(7,439,224)	(7,773,442)	(334,218)	(4.3)%
Restructuring costs	(1,278,586)	-	1,278,586	N/A
Goodwill impairment	(5,362,000)	-	5,362,000	N/A
Other income	2,859,962	291,093	2,568,869	882.5%
Loss before income taxes	$ (13,591,104)	$ (837,998)		

Revenue

Our revenue decreased during the twelve months ended June 30, 2026, as compared to the same period ended 2025, primarily due to the non-recurring $15.0 million licensing milestone payment received from the Merck Agreement during the twelve months ended June 30, 2025, as compared to the $1.2 million in revenue received from our CTx CRC collaboration agreement during the twelve months ended June 30, 2026.

Research and Development Expenses

There were no research and development ("R&D") activities being run directly by the Company for any non-BNC210 related product candidates during the strategic review for the quarters ended December 31, 2025, March 31, 2026, and June 30, 2026; however, as previously disclosed, in November 2020, we out-licensed BNC101 to Carina Biotech, and while we believe R&D activities are ongoing under the Carina Biotech License, we have neither direct control over the clinical research or development of this product, nor immediate knowledge of any such R&D activities completed during the respective reporting periods ended December 31, 2025, March 31, 2026, and June 30, 2026.

In addition, as also previously disclosed, and in our periodic reports subsequent thereto, 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; therefore, while we believe R&D activities are ongoing thereunder, we have no immediate knowledge of such activities completed in the respective reporting periods noted herein, other than what has previously been reported.

Finally, as also previously disclosed, the Company discontinued further development of BNC210 for social anxiety disorder following the results of the AFFIRM-1 trial in October 2025, and we had temporarily paused our R&D activities related to BNC 210 in PTSD while we undertook and explored a strategic transaction. While the pause in R&D activity remains in effect, the Company expects its directly funded research and development activity and expense to remain limited and substantially below the level that would be incurred if clinical development were resumed.

As noted in Note 20 of the consolidated financial statements included in this Annual Report on Form 10-K, Subsequent Events, on July 24, 2026, the Company announced a proposed Merger with Scancell Holdings plc ("Scancell"). As a result, the Company's current expectation is that either upon the consummation of the pending strategic transaction with Scancell, or with another life science company or, in the alternative, the failure to consummate a strategic alternative transaction, the Company believes the re-initiation of R&D activities, clinical trials and/or similar activities related to BNC 210 or such other company assets (e.g., the assets of a merger partner) will cause our R&D expenses to increase substantially thereafter.

General and Administrative Expenses

The decrease in general and administrative expenses in the fiscal year ended June 30, 2026 of $0.3 million, as compared to the fiscal year ended June 30, 2025, was due to decreases in headcount-related costs of $1.0 million resulting from the previously announced entity restructuring in October 2025, partially offset by increases in administrative costs of $0.7 million directly related to supporting the upcoming potential strategic event.

Goodwill Impairment

On July 1, 2026, Merck announced the cancellation of its Alzheimer's trial of MK-1167. The trial was a Phase 2 study of MK-1167, an α7 nicotinic acetylcholine receptor positive allosteric modulator, as licensed from Neuphoria. Merck stopped its study after an interim analysis indicated the drug did not meet the efficacy criteria required to justify continuing. Management determined that the suspension of the MK-1167 trial by Merck represented an impairment indicator and moved to retain an independent third-party valuation expert to perform a quantitative analysis of the carrying value of our single reporting unit and to measure its recoverability. The results of that analysis concluded an impairment existed at June 30, 2026, primarily due to downward revisions of the expected future cashflows associated with the potential commercialization of Merck's MK-1167. Accordingly, the Company recorded a goodwill impairment charge of approximately $5.4 million at June 30, 2026.

Other Income

The increase in other income of $2.6 million for the fiscal year ended June 30, 2026, as compared to the fiscal year ended June 30, 2025, was primarily due to net changes in the fair value adjustment of our contingent consideration liability and our warrant liability of $1.7 million combined with an increase in the research and development incentive award of $0.5 million, and an increase in interest income, net of $0.5 million, partially offset by an increase in the loss realized on foreign currency translation of $0.1 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, 2026, we had cash and cash equivalents of $19.9 million and an accumulated deficit of $191.8 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, 2026 and 2025

	Year Ended June 30,	
	2026	**2025**
Net cash (used in) provided by operating activities	$ (12,353,074)	$ 77,229
Net cash provided by financing activities	17,915,883	1,528,276
Effect of exchange rate on changes in cash, cash equivalents, and restricted cash	14,032	(3,750)
Net increase in cash, cash equivalents, and restricted cash	$ 5,576,841	$ 1,601,755

Operating Activities

The $12.4 million increase in net cash used in operating activities in the fiscal year ended June 30, 2026, as compared to the same period ended 2025, is primarily attributed to a $13.1 million increase in net loss combined with an unfavorable $0.9 million change in

the fair value adjustment associated with the contingent consideration liability and an unfavorable $0.8 million change in the fair value adjustment associated with the warrant liability and an unfavorable $3.5 million year-over-year change in working capital, partially offset by a $5.4 million non-cash goodwill impairment charge, a $0.3 million favorable change in the effect of foreign currency translation, and a $0.2 million increase in share-based compensation expense in the year ended June 30, 2026, as compared to the same period in 2025.

Financing Activities

The $16.4 million increase in net cash provided by financing activities to in the year ended June 30, 2026, as compared to the same period ended 2025, is primarily due to an increase in proceeds from the sale of our common stock under the ATM facility of $16.4 million combined with the collection of a subscription receivable of $0.1 million, partially offset by a year-over-year increase in equity issue costs of approximately $0.1 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") pursuant to the terms of the Sales Agreement. The Company was previously subject to the SEC's "baby shelf rules" under General Instruction I.B.6 of Form S-3; however, beginning on November 3, 2025, our public float exceeded $75.0 million. Accordingly, and as a result, pursuant to General Instruction I.B.1 of Form S-3, the Company filed a prospectus supplement amendment to increase and fix the size of the continuous ATM offering to $20,000,000. The Company will assess any necessary adjustments to the available amounts which may be sold under the ATM Sales Agreement following the filing of this annual report on Form 10-K, including whether the Company may again be subject to instruction I.B.6 of Form S-3 with respect to the ATM facility. 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 maintain working capital and for general corporate purposes; however, should the proposed Merger with Scancell not be consummated for any reason, the Company's Board of Directors will assess and update the use of proceeds set forth in an amendment to the prospectus supplement forming part of the registration statement under which shares of Common Stock under the ATM facility may be sold. During the twelve months ended June 30, 2026, we issued an aggregate of 3,398,869 shares of common stock under the ATM facility, receiving gross proceeds in the aggregate amount of approximately $18.5 million. During the twelve months 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.

Funding Requirements

Following the completion of the strategic transaction process, including the consummation of the proposed Merger with Scancell, should we or any successor entity determine to continue development of BNC210 in PTSD, or such other potential partnered product candidates which may come to fruition following the strategic review process that we may develop, such product candidates may never achieve commercialization and, as is customary in the biotechnology industry, we anticipate that we would continue to incur losses for the foreseeable future in relation thereto. In such event, we expect that our research and development expenses and our general and administrative expenses will continue to increase in the ordinary course of such matters. 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, as well as existing and potential collaborations, licenses, and other similar arrangements. Assuming continued development of such product candidates, 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 the Company's current operating plans, reflective of recent cost curtailments, the Company believes that its existing cash and cash equivalents will be sufficient to continue funding its operating activities beyond the second quarter of fiscal year 2028, 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 consolidated financial statements are issued.

The Company has based projections of operating capital requirements on the current operating plan, which management believes can be effectively implemented. The operating plan incorporates several assumptions that may prove to be incorrect, and the Company may use all available capital resources sooner than the Company expects. 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.

Assuming we do not consummate the proposed Merger with Scancell and our Board determines to continue with the research, development and commercialization of BNC210 in PTSD, or alternatively, assuming we do consummate the proposed Merger with Scancell (the proposed successor entity, which is also in the life science industry) and Scancell determines to continue such research and development activities, in either case -- due to 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 stock 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 non-current warrant liability which commits us to issuing shares to a warrant holder (Armistice, originally issued on June 4, 2024) upon the exercise of their common stock warrant; however, on July 20, 2026, the Company entered into a warrant amendment letter agreement with Armistice, pursuant to which the parties agreed that, if the "Black Scholes Value" (as defined in the Warrant) otherwise payable to Armistice upon exercise of the "Cash-Out Right" (as defined in the Warrant) in connection with the proposed Scancell Merger exceeds $3,500,000, the amount of such excess (the "Excess Amount") will be payable to Armistice, at its option and in lieu of cash, in the form of Scancell ordinary shares, Scancell ADSs, warrants to purchase Scancell ordinary shares or Scancell ADSs, or a combination thereof (the "Warrant Equity Consideration"). The number of Scancell ordinary shares constituting or underlying the Warrant Equity Consideration will equal the Excess Amount (or the portion thereof paid as Warrant Equity Consideration) divided by the Scancell Per Share Price (as defined in the Merger Agreement), multiplied by 125%. Except as expressly modified by the Warrant Letter Agreement, all other terms and conditions of the Warrant remain unmodified and in full force and effect.

Critical Accounting Policies and Estimates

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.

Significant areas where management applied estimates include:

- Goodwill impairment assessment,
- Assessing the fair value or the accompanying warrant liability, and

- Assessing the fair value of the contingent consideration liability.

Attributes requiring judgment include, but were not limited to:

- Establishing the probability of success associated with future economic inputs leveraged by the goodwill and contingent consideration calculations,
- Determining the volatility factor supporting the Black-Scholes valuation calculations, and
- Determining the discount rate leveraged by the contingent consideration fair value calculation.

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 and other areas involving estimates as of June 30, 2026.

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, 2026 and 2025:

	June 30,	
	2026	2025
	(in thousands)	
Monetary items		
Cash and cash equivalents	$ 19,866	$ 14,211
Restricted cash	—	78
Accounts receivable, non-trade	813	12
Accounts payable	(386)	(1,154)
Accrued expenses and other current liabilities	(371)	(2,950)
Operating lease liability	—	(116)
Total Monetary Items	**$ 19,922**	**$ 10,081**
Non-monetary items		
Prepaid expenses	$ 390	$ 740
Operating lease right-of-use assets, net	—	103
Intangible assets, net	4,142	4,805
Goodwill	3,498	8,639
Total Non-Monetary Items	$ 8,030	$ 14,287
Total Monetary and Non-Monetary Items	**$ 27,952**	**$ 24,368**

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 decrease in loss, and increase in 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,	
	2026	2025
10% increase (i)		
Profit or loss	$ 1,341,914	$ 1,269,444
Equity	$ 1,948,755	$ 1,747,371
10% decrease (i)		
Profit or loss	$ (1,213,844)	$ (1,714,975)
Equity	$ (1,820,685)	$ (1,747,371)

(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.

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, 2026. 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.

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, 2026 and 2025, 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 consolidated 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 Interim 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 Interim 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, 2026. Based upon that evaluation, our Interim Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2026, our disclosure controls and procedures were not effective at the reasonable assurance level due to the material weakness in our internal control over financial reporting described below.

The Company did not maintain effective controls over the evaluation of goodwill for impairment as of the reporting period end. Specifically, the Company's controls were not designed and maintained at a sufficient level of precision to identify and evaluate potential triggering events that could indicate that the carrying amount of goodwill may not be recoverable. This control deficiency resulted in the Company not timely identifying a triggering event requiring a quantitative goodwill impairment assessment. Accordingly, management concluded that this control deficiency constituted a material weakness in internal control over financial reporting as of June 30, 2026.

To remediate the material weakness identified, management is implementing a remediation plan to enhance our internal control over financial reporting. This will include strengthening our controls over the goodwill impairment evaluation process by implementing a more precise quarterly monitoring process to identify and evaluate potential qualitative and quantitative triggering events, establishing formal criteria and sensitivity thresholds to evaluate operational shifts, and enhancing the level of precision and review documentation required by management when executing these controls.

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 U.S. 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 U.S. 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, 2026. 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 our disclosure controls and procedures were not effective at the reasonable assurance level due to the material weakness in our internal control over financial reporting, described above, as of June 30, 2026.

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 the fiscal year ended June 30, 2026.

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, 2026, the name, age and position of each of our current executive officers and directors.

Name	Age	Position
Executive Officers		
Spyros Papapetropoulos	53	Interim Chief Executive Officer and Director
Tim Cunningham	64	Chief Financial Officer
Non-Executive Directors		
Miles Davies [(1)]	45	Director
Alan Fisher [(1)(2)]	73	Director
Jane Ryan, Ph.D. [(1)(2)]	67	Director
David Wilson	63	Director

(1) Audit & Risk Management Committee member

(2) Compensation 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., serves as the Company's Interim Chief Executive Officer pursuant to a Consulting Agreement with the Company (the "Consulting Agreement") effective January 1, 2026. Prior to entering into the Consulting Agreement, Dr. Papapetropoulos served as our President and Chief Executive Officer since January 5, 2023.

Effective December 31, 2025, the Company's board of directors terminated the employment agreement of Dr. Papapetropoulos, at which time Dr. Papapetropoulos ceased to serve as the full-time President and CEO of the Company. Pursuant to the terms of the employment agreement, Dr. Papapetropoulos was entitled to severance payment in an aggregate amount equal to his annual base salary, target bonus amount, and medical insurance premiums, 50% of which was paid in calendar year 2025, and the balance of such severance to be paid in partial installments in 2026 until paid in full.

Simultaneously and in connection with the termination of the foregoing employment agreement, Dr. Papapetropoulos entered into a consulting agreement with the Company (the "Consulting Agreement") effective January 1, 2026, under which Dr. Papapetropoulos will serve as the interim CEO to the Company for up to twelve months to support the execution of the Company's contemplated strategic transaction and ensure a seamless transition. Under the terms of the Consulting Agreement, Dr. Papapetropoulos will receive consulting fees equal to $800 per hour for services up to approximately 40 hours per month for his continued services, which aggregate hours shall not exceed more than twenty percent of the total hours performed while acting as the full-time CEO of the Company

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 Compensation 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 2014. Mr. Fisher served as a Corporate Finance Partner of Coopers & Lybrand from 1985 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 Compensation 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 five 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 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 either appointed or 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 [1]	Year Required to Stand for Re-Election
Miles Davies	2025	2028
Alan Fisher	2024 [2]	2026
Jane Ryan, Ph.D.	2024 [2]	2027
David Wilson	2025	2028

(1) 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 David Wilson and Miles Davies classified as the Class I directors (who were re- elected in 2025), Alan Fisher classified as the Class II director (who will stand for re-election by shareholders at our 2026 Annual General Meeting), and Spyridon Papapetropoulos (an executive director) and Jane Ryan as the Class III directors, whose terms will expire at the annual meeting of stockholders to be held in 2027.

(2) The 2024 designation as the year most recently elected for Alan Fisher and Jane Ryan is solely an indication of the Company's redomicilation in December 2024, which process was voted upon and approved by our stockholders at the 2024 annual meeting of stockholders, and at which meeting the Company's new certificate of incorporation and bylaws were also adopted, including the current staggered board of directors.

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.

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 Non-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:

- appointing and reviewing the performance and remuneration of executive management;
- involves the 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 Compensation Committee. Each of the existing members of the Audit and Risk Management Committee and Compensation 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 Compensation Committee has ever been one of our officers or employees. Except for our director Dr Papapetropoulos, who current services as a director and Interim 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 Interim 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., 14 Milliston Road, Box 195, Millis, MA 02054. 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.

In addition to having obtained and maintaining insurance for our directors and executive officers, we have also entered into indemnification agreements with our directors and executive 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 common stock to file reports relating to their ownership and changes in ownership of our common stock 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, 2026, were complied with by each person who at any time during the fiscal year ended June 30, 2026 was a director or an executive officer or held more than 10% of our common stock.

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 filing of this Annual Report 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, 2026; (ii) our two most highly compensated executive officers other than our principal executive officers who were serving as executive officers at June 30, 2026 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, 2026. Compensation information is shown for the fiscal years ending June 30, 2026 and 2025.

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 2026 and 2025 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 consolidated financial statements for the fiscal year ended June 30, 2026.

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.

2026 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. President and Chief Executive Officer	2025	$ 550,000	$ 226,875	$ -	$ 95,850	$ -	$ -	$ 50,808	$ 923,533
Spyros Papapetropoulos, M.D.[3] President and Chief Executive Officer	2026	$ 284,625	$ -	$ -	$ 272,325	$ -	$ -	$ 1,117,740	$ 1,674,690
Tim Cunningham[2] Chief Financial Officer	2025	$ -	$ -	$ -	$ -	$ -	$ -	$ 254,363	$ 254,363
Tim Cunningham Chief Financial Officer	2026	$ -	$ -	$ -	$ -	$ -	$ -	$ 325,894	$ 325,894

(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. See related party description in regard to Mr. Cunningham’s compensation and contractual arrangement with the Company.

(3) Dr. Papapetropoulos' employment with the Company terminated effective December 31, 2025. In connection with such termination, and pursuant to the terms of the applicable employment agreement, Dr. Papapetropoulos received the following

severance payments and benefits: (i) a cash payment equal to twelve months of base salary in the amount of $535,433; (ii) a cash payment equal to Dr. Papapetropoulos' target annual bonus for the fiscal year in which the termination occurred in the amount of $313,087; and (iii) payment of COBRA health benefit continuation premiums in the amount of $51,480. The target bonus component was paid in two installments on December 30, 2025 and January 15, 2026. All severance amounts were paid or accrued during the fiscal year ended June 30, 2026 and are reported in the "All Other Compensation" column above.

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, benefits, severance payments, and consulting fees;
- 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 Compensation Committee, our board of directors reviews and approves the base pay, benefits, incentive payments and equity awards of the Non-Executive Chair and other executives who report directly to the Non-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 Compensation 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 STI Awards payable to each executive is determined by our board of directors based on the Non-Executive Chair's recommendation. Our board of directors determines whether a Discretionary STI Award should be in share options, shares, and/or cash. No bonuses were paid during the twelve months ended June 30, 2026.

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, 2026:

Name	Option Awards					Stock Awards			
	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. 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	-	$ -	-	$ -
	783	-	-	$ 43.27	9/16/2030	-	$ -	-	$ -
	783	-	-	$ 43.27	12/16/2030	-	$ -	-	$ -
	783	-	-	$ 43.27	3/16/2031	-	$ -	-	$ -
	783	-	-	$ 43.27	6/16/2031	-	$ -	-	$ -
	21,750	-	-	$ 5.11	4/16/2035	-	$ -	-	$ -
	7,920	-	-	$ 8.27	8/27/2035	-	$ -	-	$ -
	-	-	783	$ 43.27	9/16/2031	-	$ -	-	$ -
	-	-	783	$ 43.27	12/16/2031	-	$ -	-	$ -
	-	-	5,250	$ 5.11	4/16/2035	-	$ -	-	$ -
	-	-	26,639	$ 8.27	8/27/2035	-	$ -	-	$ -
Tim Cunningham Chief Financial Officer	-	-	-	$ -		-	$ -	-	$ -

Key Terms of Executive Employment / Consulting 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

Dr. Papapetropoulos serves as the Company's Interim Chief Executive Officer pursuant to a Consulting Agreement with the Company (the "Consulting Agreement") effective January 1, 2026, for a period up to twelve months to support the execution of the Company's contemplated strategic transaction and ensure a seamless transition. Under the terms of the Consulting Agreement, Dr. Papapetropoulos will receive consulting fees equal to $800 per hour for services up to approximately 40 hours per month for his continued services, which aggregate hours shall not exceed more than twenty percent of the total hours performed while acting as the full-time CEO of the Company. The Consulting Agreement shall automatically terminate upon the earlier of twelve months from entry or the consummation of a strategic merger, change of control or similar transaction by the Company.

Prior to entering into the Consulting Agreement, the Company and Dr. Papapetropoulos were parties to an employment agreement effective December 16, 2022, 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 Employment Agreement which previously governed Dr. Papapetropoulos employment, benefits and compensation, which was effective through December 31, 2025, Dr. Papapetropoulos had received a 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. 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 Options (adjusted to 12,529 options on a post-redomiciliation basis in December 2024) 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.

Upon the effective termination of Dr. Papapetropoulos' Executive Employment Agreement, pursuant to the terms thereof, Neuphoria paid Dr. Papapetropoulos' severance equal to 1-times his base salary.

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 incorporated as an exhibit to this annual report on Form 10-K.

Equity Awards

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 twelve months ended June 30, 2026.

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	$ 34,271	$ 34,404	$ -	$ -	$ -	$ -	$ 68,675
Alan Fisher	$ 54,124	$ 68,804	$ -	$ -	$ 5,954	$ -	$ 128,882
Jane Ryan	$ 30,875	$ 34,404	$ -	$ -	$ 3,396	$ -	$ 68,675
David Wilson	$ 38,721	$ 34,404	$ -	$ -	$ -	$ -	$ 73,125

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 17, 2026, based on information known to Neuphoria, with respect to the beneficial ownership of shares of common stock by:

- each person known by us to be the beneficial owner of more than 5% of Neuphoria's shares of common stock;
- 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 5,411,334 of common stock outstanding as of September 17, 2026. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options, warrant(s) or other rights held by such person that are currently exercisable or will become exercisable within 60 days of September 17, 2026, 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., 14 Milliston Road, Box 195, Millis, Massachusetts 02054. 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		
Lynx1 Capital Management LP	875,328	16.2%
Directors and Named Executive Officers		
Spyridon "Spyros" Papapetropoulos, M.D. [(1)]	49,267	*
Tim Cunningham	-	-
Alan Fisher [(2)]	13,658	*
Miles Davies [(3)]	6,909	*
Jane Ryan, Ph.D. [(4)]	7,243	*
David Wilson [(5)]	6,992	*
All executive officers and directors as a group	84,069	*

* less than 1%

(1) Includes (i) 4,944 shares, and (ii) 44,323 shares that Dr. Papapetropoulos has the right to acquire pursuant to options that are exercisable as of September 17, 2026, or will become exercisable within 60 days of such date.
(2) Includes (i) 13,566 shares, and (ii) 92 shares that Mr. Fisher has the right to acquire pursuant to options that are exercisable as of September 17, 2026, or will become exercisable within 60 days of such date.
(3) Includes 6,909 shares held by Mr. Davies on September 17, 2026.
(4) Includes (i) 7,013 shares, and (ii) 230 shares that Ms. Ryan has the right to acquire pursuant to options that are exercisable as of September 17, 2026, or will become exercisable within 60 days of such date.
(5) Includes (i) 6,900 shares, and (ii) 92 shares that Mr. Wilson has the right to acquire pursuant to options that are exercisable as of September 17, 2026.

Securities Authorized for Issuance Under Equity Compensation Plans

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

Other than as set forth below, there are no transactions or series of similar transactions since July 1, 2025, 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 financial accounting, reporting, and Chief Financial Officer ("CFO") services 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 twelve months ended June 30, 2026, the Company paid Danforth a total of $843,714, of which $325,894 was for the service of Mr. Cunningham as our CFO. During the twelve months ended June 30, 2025, the Company paid Danforth a total of $734,648, of which $254,363 was for the service of Mr. Cunningham as our CFO. We believe that this agreement is on an arms-length basis.

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 then existing agreement, the Company agreed to pay to WG Partners a monthly fee of $15,000 and applicable commissions, if any, which are subject to conditions and further addendum; however, no such commissions were earned, invoiced or paid during the twelve months ended June 30, 2026 and 2025 under the terms of this agreement.

On January 20, 2026, in connection with the Company's previously announced initiation of a strategic evaluation process in October 2025, the Company and WG Partners entered into an amendment to the agreement to reflect WG Partners' continued services on behalf of the Company, alongside H.C. Wainwright & Co., the Company's lead strategic alternative transaction advisor, to assist and advise the Company in its consideration of a potential merger and acquisition, or such other strategic transaction, as the case may be. In this regard, WG Partners has extended the strategic partner outreach to territories outside of the U.S. Pursuant to the 2026 amendment, WG Partners is entitled to receive the following compensation: (i) an increase in its monthly fee from $15,000 to $20,000, plus VAT where applicable, (ii) a one-time retainer of $100,000, plus VAT where applicable, which payment was made upon entry into such 2026 amendment; and (iii) a strategic transaction success fee of $350,000, plus VAT where applicable, payable on the completion of a potential merger and acquisition transaction, if any. The agreement will continue until such time as a party gives 30 days prior written notice of termination to the other party. During the twelve months ended June 30, 2026 and 2025, WG Partners invoiced the Company for monthly stipend fees of $219,981 and $148,971, respectively. We believe that this agreement, as amended, was negotiated and entered into 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 2026 and 2025, with respect to our consolidated financial statements prepared in accordance with U.S. GAAP. The following table presents fees for professional services rendered by Wolf & Company, P.C. for the twelve months ended June 30, 2026 and 2025.

	Year Ended June 30,	
	2026	**2025**
Audit and review fees	$ 323,500	$ 258,000
Audit-related fees	45,000	89,000
Tax fees	-	-
All other fees	-	-

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)
2.3	Agreement and Plan of Merger, dated as of July 23, 2026, by and among Scancell Holdings plc, Scancell Merger Sub, Inc. and Neuphoria Therapeutics Inc. (incorporated by reference to Exhibit 2.1 to Neuphoria Therapeutics Inc.'s Current Report on Form 8-K, filed on July 24, 2026)
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)
3.3	Certificate of Designation of Series A Preferred Stock filed with the Secretary of State of the State of Delaware on October 27, 2025 (incorporated by reference to Exhibit 3.1 to Neuphoria Therapeutics Inc.'s Current Report on Form 8-K, filed on October 27, 2025)
4.1	Rights Agreement, dated as of October 27, 2025 between Neuphoria Therapeutics Inc. and Computershare Trust Company, N.A. (incorporated by reference to Exhibit 4.1 to Neuphoria Therapeutics Inc.'s Current Report on Form 8-K, filed on October 27, 2025)
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), amended on January 20, 2026 (as described in the annual report)
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)
10.27	Consulting Agreement, effective January 1, 2026, between the Company and Mr. Papapetropoulos (incorporated by reference to Exhibit 10.1 to Neuphoria Therapeutics Inc.'s Current Report on Form 8-K, filed on January 7, 2026)
10.28	Form of Company Voting and Support Agreement (incorporated by reference to Exhibit 10.1 to Neuphoria Therapeutics Inc.'s Current Report on Form 8-K, filed on July 24, 2026)
10.29	Form of Parent Voting and Support Deed (incorporated by reference to Exhibit 10.2 to Neuphoria Therapeutics Inc.'s Current Report on Form 8-K, filed on July 24, 2026)
10.30	Form of Lock-Up Agreement (incorporated by reference to Exhibit 10.3 to Neuphoria Therapeutics Inc.'s Current Report on Form 8-K, filed on July 24, 2026)
10.31	Form of Contingent Value Rights Agreement (incorporated by reference to Exhibit 10.4 to Neuphoria Therapeutics Inc.'s Current Report on Form 8-K, filed on July 24, 2026)
10.32	Form of Subscription Agreement, by and among Scancell Holdings plc, Scancell Merger Sub, Inc., Neuphoria Therapeutics Inc. and institutional investors (incorporated by reference to Exhibit 10.5 to Neuphoria Therapeutics Inc.'s Current Report on Form 8-K, filed on July 24, 2026)
10.33	Form of Subscription Agreement, by and among Scancell Holdings plc, Scancell Merger Sub, Inc., Neuphoria Therapeutics Inc. and individual investors (incorporated by reference to Exhibit 10.6 to Neuphoria Therapeutics Inc.'s Current Report on Form 8-K, filed on July 24, 2026)

10.34	Letter Agreement, dated as of July 20, 2026, between Neuphoria Therapeutics Inc. and Armistice Capital Master Fund Ltd. (incorporated by reference to Exhibit 10.7 to Neuphoria Therapeutics Inc.'s Current Report on Form 8-K, filed on July 24, 2026)
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 18, 2026	By:	*/s/ Spyridon Papapetropoulos, M.D.*
	Name:	Spyridon Papapetropoulos
	Title:	Interim Chief Executive Officer and Director
Date: September 18, 2026	By:	*/s/ Timothy Cunningham*
	Name:	Timothy Cunningham
	Title:	Chief Financial Officer and Principal Financial Officer
Date: September 18, 2026	By;	*/s/ Miles Davies*
	Name:	Miles Davies
	Title:	Director
Date: September 18, 2026	By:	*/s/ Alan Fisher*
	Name:	Alan Fisher
	Title:	Director
Date: September 18, 2026	By:	*/s/ Jane Ryan*
	Name:	Jane Ryan
	Title:	Director
Date: September 18, 2026	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, 2026, and 2025, the related consolidated statements of operations and other comprehensive income (loss), changes in shareholders' equity, and cash flows for each of the two years in the period ended June 30, 2026, 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, 2026 and 2025, and the results of its operations and its cash flows for each of the two years in the period ended June 30, 2026, 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 18, 2026

Neuphoria Therapeutics Inc.
Consolidated Balance Sheets

	June 30, 2026	June 30, 2025
Assets		
Current assets		
Cash and cash equivalents	$ 19,865,531	$ 14,210,745
Accounts receivable, non-trade	813,431	11,948
Restricted cash	-	77,945
Prepaid expenses	389,772	740,193
Total current assets	21,068,734	15,040,831
Property and equipment, net	-	2,771
Intangible assets, net	4,142,060	4,804,791
Operating lease right-of-use assets	-	102,612
Goodwill	3,498,222	8,638,609
Total assets	$ 28,709,016	$ 28,589,614
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 385,584	$ 1,154,369
Accrued expenses and other current liabilities	370,997	2,950,077
Operating lease liability	-	116,314
Total current liabilities	756,581	4,220,760
Contingent consideration	1,025,301	1,169,675
Deferred tax liability	355,940	495,113
Accompanying warrant liability	1,971,172	3,701,492
Total liabilities	4,108,994	9,587,040
Commitments and contingencies (Note 18)		
Shareholders' equity		
Common stock, $0.00001 par value, 5,411,334 and 1,978,460 shares issued and outstanding at June 30, 2026 and 2025, respectively	54	19
Additional paid-in capital, net of subscription receivable	218,461,772	200,194,324
Accumulated other comprehensive loss, net of tax	(2,063,170)	(2,845,066)
Accumulated deficit	(191,798,634)	(178,346,703)
Total shareholders' equity	24,600,022	19,002,574
Total liabilities and shareholders' equity	$ 28,709,016	$ 28,589,614

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,	
	2026	2025
Revenue		
License revenue	$ -	$ 15,649,448
Collaborative arrangement revenue	1,174,165	-
Total revenue	1,174,165	15,649,448
Operating expenses		
Research and development	3,545,421	9,005,097
General and administrative	7,439,224	7,773,442
Restructuring costs	1,278,586	-
Goodwill impairment	5,362,000	-
Total operating expenses	17,625,231	16,778,539
Loss from operations	(16,451,066)	(1,129,091)
Other income (loss)		
Interest income, net	665,571	166,498
Loss on foreign currency transactions	(535,722)	(414,996)
Research and development incentive award	800,904	299,905
Gain on fair value adjustments	1,929,209	239,686
Total other income	2,859,962	291,093
Loss before income taxes	(13,591,104)	(837,998)
Income tax benefit	139,173	468,366
Net loss	(13,451,931)	(369,632)
Other comprehensive income		
Unrealized gain on foreign currency translation	781,896	168,529
Total other comprehensive income	781,896	168,529
Comprehensive loss	$ (12,670,035)	$ (201,103)
Net loss per share - basic and diluted	$ (3.06)	$ (0.23)
Weighted-average common shares outstanding - basic and diluted	4,395,776	1,622,924

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 Receivable	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount					
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
Issuance of common stock in connection with our ATM facility, net of offering costs of $0.6 million	3,398,869	35	-	17,821,163	-	-	17,821,198
Issuance of common stock, vested restricted stock unit awards	34,005	-	-	-	-	-	-
Collection of subscription receivable	-	-	94,685	-	-	-	94,685
Share-based compensation	-	-	-	351,600	-	-	351,600
Other comprehensive income	-	-	-	-	781,896	-	781,896
Net loss	-	-	-	-	-	(13,451,931)	(13,451,931)
Balance at June 30, 2026	5,411,334	$ 54	$ -	$ 218,461,772	$ (2,063,170)	$ (191,798,634)	$ 24,600,022

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

Neuphoria Therapeutics Inc.
Consolidated Statement of Cash Flows

	Year Ended June 30,	
	2026	2025
Cash flows from operating activities:		
Net loss	$ (13,451,931)	$ (369,632)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Share-based compensation	351,600	163,772
Goodwill impairment	5,362,000	-
Depreciation and amortization expense	662,955	662,890
Non-cash rent expense	102,612	114,363
Change in fair value of accompanying warrant liability	(1,730,321)	(956,340)
Change in fair value of contingent consideration	(198,888)	716,654
Effect of foreign currency remeasurement	603,313	242,348
Changes in assets and liabilities:		
Accounts receivable, non-trade	(801,483)	114,936
Prepaid expenses	350,421	(453,058)
Accounts payable	(768,785)	(917,663)
Accrued expenses and other current liabilities	(2,579,080)	1,486,656
Operating lease liabilities	(116,314)	(123,304)
Deferred tax liability	(139,173)	(468,427)
Contingent consideration	-	(133,080)
Other non-current liabilities	-	(2,886)
Net cash (used in) provided by operating activities	(12,353,074)	77,229
Cash flows from financing activities:		
Proceeds from the sale of equity, net of issuance costs of $0.6 million	17,915,883	-
Proceeds from the sale of equity, net of subscriptions receivable of $0.1 million and issuance costs of $0.1 million	-	1,528,276
Net cash provided by financing activities	17,915,883	1,528,276
Effect of exchange rate on changes in cash, cash equivalents, and restricted cash	14,032	(3,750)
Net increase in cash, cash equivalents, and restricted cash	5,576,841	1,601,755
Cash, cash equivalents, and restricted cash, beginning of period	14,288,690	12,686,935
Cash, cash equivalents, and restricted cash, end of period	$ 19,865,531	$ 14,288,690
Reconciliation of cash, cash equivalents, and restricted cash:		
Cash and cash equivalents	$ 19,865,531	$ 14,210,745
Restricted cash	-	77,945
Total cash, cash equivalents, and restricted cash	$ 19,865,531	$ 14,288,690
Supplemental cash flow data:		
Cash paid for interest expense	$ 3,857	$ 17,433

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”) 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's lead drug candidate, BNC210, an oral, proprietary, selective negative allosteric modulator of the α7 nicotinic acetylcholine receptor for the treatment of post-traumatic stress disorder ("PTSD"). BNC210 is a first-of-its-kind, 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.

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

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

Restructuring Costs

On October 20, 2025, the Company announced that the AFFIRM-1 Phase 3 trial of BNC210 for the acute treatment of social anxiety disorder did not meet its primary endpoint. Based on these results, the Company announced that it has discontinued the BNC210 SAD program and has paused the BNC210 PTSD program while it continues to undertake a comprehensive strategic review of its operations and portfolio. During the twelve months ended June 30, 2026, the Company terminated all but one employee, terminated its facility leases, and cancelled or paused, as applicable, its research and development activities while it seeks to identify a partner with which to execute a strategic merger and/or such other transaction(s), if any, for the benefit of existing shareholders of Neuphoria. See Note 3 for more information.

Liquidity and Going Concern

Since inception, we have incurred significant operating losses and expect to continue to incur net losses for the foreseeable future. As of June 30, 2026, the Company had working capital of $20.3 million, an accumulated deficit of $191.8 million, and cash and cash equivalents of $19.9 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.

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 net losses of $13.5 million and $0.4 million for the twelve months ended June 30, 2026 and 2025, respectively. The Company also used $12.4 million of cash in operating activities during the twelve months ended June 30, 2026.

Based upon the Company’s current operating plans, reflective of recent cost curtailments, the Company believes that its existing cash and cash equivalents will be sufficient to continue funding its operating activities beyond the second quarter of fiscal year 2028, 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.

Although the Company believes its existing cash and cash equivalents will be sufficient to fund operations beyond the assessment period and it 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.

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.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker ("CODM") in deciding how to allocate resources and in assessing performance. The CODM of the Company is the Interim Chief Executive Officer. The Company operates as a single operating and reporting 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 disorders with high unmet medical need. The CODM evaluates the operating performance based on net income (loss) as reported on the consolidated statement of operations. The measure of the operating segment assets is reported on the consolidated balance sheet as total assets.

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. The underlying facility lease expired during the year ended June 30, 2026, according to its terms, resulting in no funds being held as restricted cash on that date. The previously restricted amounts represented the security deposit associated with the Company's previous 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 4 for disclosure of other fair value measurements.

Goodwill

Goodwill is not subject to amortization. The Company tests the carrying amount of its goodwill for recoverability on an annual basis on June 30, or more frequently if events or changes in circumstances indicate that the asset might be impaired. We monitor for indications of impairment throughout the year and perform qualitative and quantitative impairment tests as deemed necessary by management. If the fair value estimate is less than the carrying value, goodwill is considered impaired for the amount by which the carrying amount exceeds the reporting unit's fair value, and a charge is reported in impairment of goodwill in the Company's consolidated statements of operations. If the fair value is greater than the carrying value, then the carrying value is deemed to be recoverable and no further action is required. Our estimates of fair value may give consideration to market approaches utilizing the Company's market capitalization, adjusted for implied control premiums based on transactions for comparable entities, and utilizing the value of the Company in other recent transactions,

During the fourth quarter of fiscal 2026, we recorded an impairment loss related to goodwill of approximately $5.4 million. See Note 7 for further information.

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, 2026 and 2025, 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 Company 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. 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 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 may have lease agreements with lease and non-lease components. As allowed under Accounting Standards Codification ("ASC") Topic 842, *Leases* ("Topic 842"), the Company generally elects to not separate lease and non-lease components for any leases involving real estate and office equipment classes of assets and, as a result, would account 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. See *License Revenue* (below) for more information relative to our contracts with customers.

Under ASC Topic 808, *Collaborative Arrangements* ("Topic 808"), a collaborative arrangement is a contractual arrangement under which two or more parties actively participate in a joint operating activity and are exposed to significant risks and rewards that depend on the commercial success of the activity. The Company evaluates arrangements to determine whether they meet the definition and scope of a collaborative arrangement. Arrangements within the scope of ASC 808 may contain components that are subject to other authoritative accounting guidance, including ASC 606. Transactions with a counterparty that is a customer in the context of a distinct good or service are accounted for in accordance with Topic 606. Transactions that are not within the scope of Topic 606 are accounted for in accordance with other applicable authoritative accounting guidance, as appropriate. Costs incurred and revenue generated from transactions with third parties are presented in accordance with the applicable principal-versus-agent guidance. Payments between

participants are presented in the consolidated statement of operations based on the applicable accounting guidance for the underlying transaction.

License Revenue

The Company assesses its license arrangements within the scope of Topic 606 in accordance with this framework as follows:

- 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 and collaboration 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 Matters

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 and record translation adjustment in accumulated other comprehensive loss. 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 income (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 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 December 2023, the FASB issued ASU No. 2023-09, *Improvements to Income Tax Disclosures* ("ASU 2023-09"). ASU 2023-09 requires more detailed income tax disclosures. The guidance requires entities to disclose disaggregated information about their effective tax rate reconciliation as well as expanded information on income taxes paid by jurisdiction. The disclosure requirements will be applied on a prospective basis, with the option to apply them retrospectively. The Company adopted ASU 2023-09 prospectively in 2026 and it did not have a material impact on the Company's consolidated financial statements (see Note 14).

Recently Issued Accounting Pronouncements Not Yet Adopted

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. Restructuring Costs

In October 2025, Management committed to a plan to discontinue or pause, with respect to BNC210 in SAD and PTSD, its research and development activities while it seeks to identify a partner with which to execute a strategic merger and/or such other transaction(s), if any, for the benefit of existing shareholders of Neuphoria. As part of the restructuring initiative, the Company terminated its facility leases, wrote off the remaining carrying value of the right-of-use asset, derecognized the associated operating lease liability, and terminated substantially all of its employees. A liability equivalent to the derecognized lease liability has been included in Accrued restructuring expenses. The write-offs are included in restructuring costs in the consolidated statements of operations and other comprehensive income (loss) for the twelve months ended June 30, 2026.

Included in total restructuring costs are the following expenses:

	Twelve Months Ended June 30, 2026
Employee termination costs	$ 1,411,955
Impairment of right-of-use asset	47,608
Other restructuring costs	437,994
Refundable credits on contract terminations	(618,971)
Total restructuring costs	$ 1,278,586

Restructuring reserves included in accrued expenses and other current liabilities on the consolidated balance sheet are as follows:

	Restructuring Costs
Restructuring liability at June 30, 2025	$ -
Restructuring costs	1,278,586
Restructuring payments	(1,220,255)
Restructuring liability at June 30, 2026	$ 58,331

Note 4. 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, 2026			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Contingent consideration	$ -	$ -	$ 1,025,301	$ 1,025,301
Accompanying warrant liability	-	-	1,971,172	1,971,172
Total liabilities measured at fair value	$ -	$ -	$ 2,996,473	$ 2,996,473

	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

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 12) 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 17 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 Warrants Liability
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
Change in fair value, net of foreign currency effect	(144,374)	(1,730,320)
Balance at June 30, 2026	$ 1,025,301	$ 1,971,172

The Company evaluates transfers between levels at the end of each reporting period. There were no transfers between levels during the periods presented.

Note 5. Accounts Receivable, Non-trade

Accounts receivable, non-trade consist of the following:

	June 30, 2026	June 30, 2025
Research and development incentives receivable	$ 810,778	$ -
GST receivables	2,653	11,711
Interest receivable	-	237
Total accounts receivable, non-trade	$ 813,431	$ 11,948

Note 6. 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 lease expired according to its terms in May 2026.

The Company accounted for the Greenhill Lease under ASC 842, recognizing a right-of-use ("ROU") asset and a corresponding lease liability representing future rent payment obligations. The ROU asset was initially measured based on the present value of future lease payments and subsequently amortized over the lease term.

In October 2025, the Company committed to a plan to exit its Australian facility as part of a restructuring plan as approved by the Company's board of directors. The leased facility ceased being used for any business purpose and the Company did not sublease the space during the remainder of the lease term. Accordingly, under ASC 360, *Property, Plant, and Equipment*, and ASC 842, the carrying value of the associated right-of-use asset was evaluated for abandonment, and the remaining carrying amount of less than $0.1 million was derecognized. The lease liability of approximately $0.1 million was also derecognized.

The resulting write-off of the right-of-use asset is recorded in restructuring costs in the consolidated statements of operations and other comprehensive income (loss) for the twelve months ended June 30, 2026.

Variable lease expense for the premises primarily consisted of common area maintenance and other operating costs.

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,	
	2026	2025
Operating lease costs		
Research and development	$ 28,749	$ 44,148
General and administrative	36,536	49,727
Total	$ 65,285	$ 93,875

Note 7. Goodwill

Goodwill represents the excess of the purchase consideration over the fair value of the identifiable net assets acquired and is primarily attributable to expected synergies from combining the acquired operations with the Company's existing business, the value of the acquired assembled workforce, and other intangible benefits that did not qualify for separate recognition as identifiable intangible assets under ASC 805. The Company has only one reporting unit: drug development. Management tests annually whether goodwill has suffered any impairment. All goodwill exists within the drug development reporting unit.

The following table summarizes goodwill, net of the effect of foreign currency exchange adjustments and the goodwill impairment charge, for the twelve months ended June 30, 2026 and 2025, respectively:

Acquisition	June 30, 2026	June 30, 2025
Iliad Chemicals Pty Ltd acquisition	$ 4,700,360	$ 4,478,747
Eclipse Therapeutics, Inc. acquisition	4,159,862	4,159,862
	$ 8,860,222	$ 8,638,609
Goodwill impairment	(5,362,000)	-
	$ 3,498,222	$ 8,638,609

Carrying amount at June 30, 2025	$ 8,638,609
Foreign currency exchange differences	221,613
Goodwill impairment	(5,362,000)
Carrying amount at June 30, 2026	$ 3,498,222
Carrying amount at June 30, 2024	$ 8,690,018
Foreign currency exchange differences	(51,409)
Carrying amount at June 30, 2025	$ 8,638,609

As stated in Note 2, *Summary of Significant Accounting Policies*, the Company tests the carrying amount of its goodwill for recoverability on an annual basis on June 30, or more frequently if events or changes in circumstances indicate that the asset might be impaired. We monitor for indications of impairment throughout the year and perform qualitative and quantitative impairment tests as deemed necessary by management.

On July 1, 2026, Merck announced the cancellation of its Alzheimer’s trial of MK-1167. The trial was a Phase 2 study of MK-1167, an α7 nicotinic acetylcholine receptor positive allosteric modulator, as licensed from Neuphoria. Merck stopped its study after an interim analysis indicated the drug did not meet the efficacy criteria required to justify continuing. Management determined that the suspension of the MK-1167 trial by Merck represented an impairment indicator and moved to retain an independent third-party valuation expert to perform a quantitative analysis of the carrying value of our single reporting unit. The June 30, 2026 valuation applied a market approach with adjustments, as necessary, to market capitalization data for implied control premiums. The results of

that analysis concluded an impairment existed at June 30, 2026, primarily due to downward revisions of the expected future cashflows associated with the potential commercialization of Merck's MK-1167. Accordingly, the Company recorded a goodwill impairment charge of approximately $5.4 million at June 30, 2026.

The Company has no accumulated goodwill impairment losses as of June 30, 2026 except for the goodwill impairment recorded as a result of the Merck cancellation.

Note 8. Intangible Assets

Intellectual Property

The acquired intellectual property relates to cancer stem cell technology and is carried at its cost on the date of acquisition, less accumulated amortization. There was no impairment identified by the Company at June 30, 2026 or 2025.

	Cancer Stem Cell Technology
Carrying amount at June 30, 2025	$ 4,804,791
Amortization expense	(662,731)
Carrying amount at June 30, 2026	$ 4,142,060
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 straight-line basis over its estimated useful life of 20 years. There is currently no internally generated intellectual property capitalized. The Company concluded a quantitative assessment was not required with respect to the financial reporting period ended June 30, 2026 as no events occurred or circumstances changed that would more likely than not reduce the fair value of the acquired intellectual property below its carrying amount.

Note 9. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	June 30, 2026	June 30, 2025
Research and development expenses	$ 15,264	$ 1,656,280
Accrued restructuring expenses	58,331	-
Salary and benefits	21,892	794,836
Professional and consulting fees	188,000	152,306
Insurance	-	278,149
EDA Loan	34,345	32,750
Other	53,165	35,756
Total accrued expenses and other current liabilities	$ 370,997	$ 2,950,077

Note 10. 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, 2026, there were 807,491 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 table summarizes the weighted-average assumptions used in calculating the fair value of the awards granted during the years ended June 30, 2026 and 2025:

	Year Ended June 30,	
	2026	**2025**
Expected term (in years)	6.0	5.8
Expected volatility	86.5%	79.6%
Risk-free interest	3.8%	3.8%
Dividend yield	-%	-%

The following table summarizes employee and non-employee stock option activity for the year ended June 30, 2026:

	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, 2025	91,211	$	88.79	6.15	$	-
Granted	51,839	$	8.27	9.16	$	-
Lapsed	(27,140)	$	14.68	-	$	-
Outstanding as of June 30, 2026	115,910	$	70.13	6.57	$	-
Options exercisable as of June 30, 2026	82,455	$	94.77	5.63	$	-

[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, 2026 of $4.37 and the per share exercise price of the underlying options.

As of June 30, 2026, there was approximately $0.3 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 1.31 years.

During the twelve months ended June 30, 2026 and 2025, the Company recognized total share-based compensation expense of approximately $0.2 million and $0.1 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 weighted average grant date fair value of options granted during the twelve months ended June 30, 2026 and 2025, was $7.88 and $4.58 per option, respectively.

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 recipient's 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 the underlying shares are vested.

The table below summarizes activity relating to RSUs for the twelve months ended June 30, 2026:

	Number of Units	Weighted-Average Grant Date Fair Value
Outstanding at June 30, 2025	33,915	$ 5.11
Vested / Settled	(33,915)	5.11
Granted	42,684	4.03
Outstanding at June 30, 2026	42,684	$ 4.03

The Company recognized approximately $0.2 million and $0.1 million of stock-based compensation expense associated with the RSUs for the twelve months ended June 30, 2026 and 2025, respectively. As of June 30, 2026, the outstanding RSUs had unamortized stock-based compensation expense of $0.1 million with a weighted-average remaining recognition period of 0.5 years and an aggregate intrinsic value of $0.2 million.

Note 11. 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 stockholders 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.

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. No shares of preferred stock are issued or outstanding as of June 30, 2026.

Shareholder Rights Agreement

On October 25, 2025, the Board of Directors (the “Board”) of Neuphoria Therapeutics Inc. declared a dividend of one right (“Right”) to purchase one-thousandth of one share of the Company’s newly designated Series A Preferred Stock, par value $0.00001 per share (each, a “Preferred Share” and collectively, the “Preferred Shares”), for each outstanding share of common stock, par value $0.00001 per share, of the Company to the stockholders of record as of the close of business on October 27, 2025 (the “Record Date”). The Company also adopted a limited duration stockholder rights plan (the “Rights Plan”), effective immediately, as set forth in the Rights Agreement, dated as of October 27, 2025 (the “Rights Agreement”), by and between the Company and Computershare Trust Company, N.A., as Rights Agent. The Rights Agent currently serves as the Company’s transfer agent with respect to the Company

Common Stock and also has been appointed transfer agent with respect to the Preferred Shares, if any, that may be issued pursuant to the exercise of rights under the Rights Agreement. The Rights will expire on October 27, 2026, unless the rights are earlier redeemed or exchanged by the Company. The Company does not have any obligation under the Rights Agreement to seek stockholder approval for the Rights Plan. In connection with the Rights Plan, the Company also filed a Certificate of Designation with the Secretary of State of the State of Delaware on October 27, 2025 with respect to the Series A Preferred Stock shares issuable under the Rights Plan. Per the terms of the Rights Plan, the purchase price for each 1/1000th of a Preferred Share pursuant to the exercise of a Right shall initially be $85.00. There were no triggering events under the Shareholders Rights Plan during the twelve months ended June 30, 2026.

Preferred Share Provisions:

Each Preferred Share, if issued:

- will not be redeemable;
- when, as and if any dividend is declared on Company Common Stock, entitle the holder to quarterly dividend payments in an amount per share equal to 1,000 times the aggregate per share amount of all cash dividends, and 1,000 times the aggregate per share amount, payable in kind, of all non-cash dividends or other distributions other than a dividend payable in Company Common Stock or a subdivision of the outstanding Company Common Stock, by reclassification or otherwise, declared on Company Common Stock since the immediately preceding quarterly dividend payment date or, with respect to the first date when quarterly dividends are payable in cash, since the first issuance of any share or fraction of a share of Series A Preferred Stock;
- will entitle the holder upon liquidation either to receive a preferential liquidation payment of the greater of (a) $1,000 per Series A Preferred Share, plus an amount equal to accrued and unpaid dividends and distributions thereon, whether or not declared, to the date of such payment, and (b) an aggregate amount per Series A Preferred Share equal to 1,000 times the aggregate amount to be distributed per share to holders of Company Common Stock plus an amount equal to any accrued and unpaid dividends on such Series A Preferred Shares;
- will have the same voting power as 1,000 shares of Company Common Stock;
- if shares of Company Common Stock are exchanged via merger, consolidation, or a similar transaction, will entitle the holder to a per share payment equal to the payment made on 1,000 shares of Company Common Stock; and
- will rank junior to any other series of the Company's preferred stock in the event such other preferred stock is issued by the Company, unless the terms of any such series provide otherwise.

The value of one one-thousandth (1/1,000th) interest in a Series A Preferred Share is intended to approximate the value of one share of Company Common Stock.

Note 12. Warrant

The following table summarizes warrant activity for the twelve months ended June 30, 2026 and 2025:

	Number of Warrant Shares	Weighted Average Exercise Price USD
Balance at June 30, 2024	1,579,086	$ 7.92
Exercised	(524,705)	-
Balance at June 30, 2025	1,054,381	$ 11.88
Exercised	-	-
Balance at June 30, 2026	1,054,381	$ 11.88

At June 30, 2026, the fair value of the accompanying warrant, which is required to be subsequently measured pursuant to U.S. GAAP, was calculated using a probability-adjusted weighted average Black-Scholes calculation which considered scenarios and outcomes associated with the likely successful closing of the publicly announced merger transaction. At June 30, 2025, the fair value of the

accompanying warrant was calculated using a standalone Black-Scholes calculation in accordance with the facts and circumstances that existed on that date.

The following assumptions were utilized at June 30, 2026 and 2025, respectively:

	Year Ended June 30, 2026	Year Ended June 30, 2025
Expected term (in years)	3	4
Expected volatility	100% - 112.7%	79.6%
Risk-free interest	4.2%	3.7%
Dividend yield	—%	—%

The classification, expiration date, and exercise price of the shares of common stock underlying the outstanding warrant at June 30, 2026 is as follows:

	Number of Warrant Shares Outstanding	Exercise Price	Expiration Date	Classification
2024 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, 2026 is 2.93 years.

Note 13. Revenue

Cancer Therapeutics Cooperative Research Centre

The Company became a multi-party participant via agreement (the "Participants Agreement") in the Australian Government-supported Cancer Therapeutics Cooperative Research Centre (“CTx CRC” or "CRC") in 2007. The CRC collaborative arrangement was established to support oncology research, development, and commercialization activities. Approximately seventeen participants contributed cash, personnel, intellectual property, and in-kind resources during the initial phases of CRC’s existence. The Company holds an approximate 4.65% participation interest in CRC.

Beginning in 2016, the CRC became self-funding through licensing and commercialization activities with third-party customers. The CRC, rather than the Company, contracts with those third-party customers and recognizes revenue from those arrangements. Under the Participants Agreement and related commercialization agreements, participants retain contractual rights to participate in future commercialization proceeds generated from CRC-developed technologies in accordance with their participation interests. Accordingly, although the Company no longer contributes cash to CRC, it retains continuing contractual rights to receive distributions arising from successful commercialization activities. The Company is now a passive participant whose contractual rights are limited to receiving distributions based upon its participation interest.

The Company accounts for its participation in the CRC Participants Agreement as a collaborative arrangement under ASC 808, which provides guidance on presentation and disclosure but generally does not prescribe comprehensive recognition principles. The Company does not account for CRC distributions under ASC 606, because CRC is not a customer of the Company, the Company does not transfer goods or services to CRC in exchange for the distributions, and the Company has no performance obligations to the third-party licensees that contract with CRC.

The Company recognizes CRC distributions when its contractual right to receive the distribution becomes fixed or determinable and collection is reasonably assured. Amounts recognized from CRC distributions are presented in revenue and are separately disclosed because such amounts do not represent revenue recognized under ASC 606. Although the Company has become a passive participant in recent years, management believes the appropriate assessment is based upon the contractual arrangement as a whole. The Company's continuing distribution rights exist because of its historical participation and continuing participation interest rather than because CRC currently purchases goods or services from the Company. These activities demonstrate participation in the underlying operating activity rather than a customer-vendor relationship. This accounting policy decision to report distributions from CRC as revenue is analogous to the Company’s accounting for historical contributions to CRC which were included as costs of operations and expensed as part of research and development as incurred.

The Company recognized revenue associated with the CRC arrangement of approximately $1.2 million during the twelve months ended June 30, 2026. The Company did not receive any distributions from CRC during the twelve months ended June 30, 2025.

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 A$2.0 million and A$3.0 million in certain development and regulatory milestone payments if Carina Biotech advances the development of the therapy to a Phase 2 or Phase 3 trial, respectively. 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 approximately $0.7 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). The Company did not receive any milestone payments from Carina Biotech during the twelve months ended June 30, 2026.

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 an aggregate of $450 million in milestone payments comprised of $275 million for the achievement of certain development milestones and $175 million in potential commercial milestones, plus royalties on net sales of any licensed medicines.

The Company evaluated the Merck Agreement in accordance with the provisions of 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.

The Company did not receive any milestone payments from Merck during the twelve months ended June 30, 2026.

Note 14. Income Taxes

The components of loss before income taxes for the years ended June 30, 2026 and 2025 are as follows:

	June 30,	
	2026	**2025**
U.S.	$ (8,254,064)	$ (7,111,507)
Non - U.S.	(5,337,040)	6,273,509
Total	$ (13,591,104)	$ (837,998)

The components of income tax benefit for the years ended June 30, 2026 and 2025 are as follows:

	June 30,	
	2026	2025
Current:		
Current, Non - U.S.	$ -	$ (61)
Total current	$ -	$ (61)
Deferred:		
Deferred, U.S.	$ 1,533,035	$ 532,004
Deferred, state	474,651	113,698
Deferred, Non - U.S.	1,084,443	(925,293)
Less: Change in valuation allowance	(2,952,956)	748,018
Total deferred	$ 139,173	$ 468,427
Total income tax benefit	$ 139,173	$ 468,366
Effective income tax rate	1.0%	55.9%

The items accounting for the difference between income taxes computed at the U.S. federal statutory rate and our effective rate for the year ended June 30, 2026, pursuant to the requirements of ASU 2023-09, are as follows:

	For the Year Ended June 30, 2026	
Federal statutory tax rate	$ 2,854,131	21.0%
Effect of:		
State and local income tax, net of federal income tax effect [(1)]	474,652	3.5%
Foreign tax effects (Australia):		
Statutory tax rate difference	97,967	0.7%
Exempt income from government assistance (R&D)	202,695	1.5%
Net gain arising on changes in fair value of contingent consideration	50,335	0.4%
Research & development expenditures	(465,964)	(3.4)%
Project costs	230,030	1.7%
Temporary difference not recorded as an asset	455,162	3.3%
Change in valuation allowance	(1,084,443)	(8.0)%
Goodwill impairment	(606,454)	(4.5)%
Other	(104)	-%
Changes in U.S. valuation allowance	(1,911,267)	(14.1)%
Nontaxable or nondeductible items:		
Warrant arrant liability fair value adjustment	363,367	2.7%
Goodwill impairment	(519,565)	(3.8)%
Other adjustments	(1,369)	-%
Total income tax benefit	$ 139,173	1.0%

(1) State taxes in Massachusetts made up the majority (greater than 50 percent) of the tax effect in this category.

The following table presents a reconciliation of the provision (benefit) for income taxes to taxes computed at the U.S. federal statutory rate before adoption of ASU 2023-09:

	For the Year Ended June 30, 2025	
Loss before taxes	$ (837,998)	
Income tax rate reconciliation:		
Benefit at statutory rate	$ 175,980	21.0%
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%
Net gain arising on changes in fair value of contingent consideration	(183,079)	(21.8)%
Share-based compensation	(11,463)	(1.4)%
Research & development expenditures	(231,386)	(27.6)%
Project costs	301,513	36.0%
Temporary difference not recorded as an asset	(270,470)	(32.3)%
Withholding taxes deducted from fees overseas	(62)	-%
Effect of different tax rates of subsidiaries operating in other jurisdictions	(97,032)	(11.6)%
Change in valuation	748,018	89.3%
RTP Eclipse true-up	154,211	18.4%
Other	(571)	(0.1)%
Total income tax benefit	$ 468,366	55.9%

The principal components of the Company's deferred tax liabilities at June 30, 2026 and 2025 are as follows:

	June 30,	
	2026	2025
Deferred tax assets:		
U.S. Net Operating Loss	$ 2,823,662	$ 962,686
Non - U.S. Net Operating Loss	22,086,265	23,891,685
Undeducted Capital Expenditures	698,922	1,418,616
Provision for leave	-	78,891
Accrued Expenses	2,512	9,091
Patent costs	410,173	470,594
Unrealized loss on foreign currency	127,126	-
U.S. tax Credit	32,061	32,061
Other adjustments	-	93,152
Total deferred tax assets	26,180,721	26,956,776
Deferred tax liabilities		
Eclipse acquisition	1,131,611	1,312,669
Provision for leave	4,140	-
Other adjustments	15	-
Accrued interest income	-	60
Total deferred tax liability	1,135,766	1,312,729
Less: Valuation allowance	25,400,895	26,139,160
Net deferred tax liability	$ 355,940	$ 495,113

At June 30, 2026 and 2025, the Company recorded valuation allowances of approximately $25.4 million and $26.1 million, respectively, against its deferred tax assets since in the judgment of management, these assets are not more than likely to be realized. The decrease in the valuation allowance at June 30, 2026, as compared to June 30, 2025, was due to changes in the foreign currency exchange rates between the U.S. dollar and the Australian dollar.

At June 30, 2026, the Company had a Net Operating Loss ("NOL") carryforward of approximately $123.5 million. The Company has U.S. NOL carryforwards of approximately $1.0 million, with a 20-year carryforward that will start expiring in 2032 and approximately $9.6 million with an indefinite carryforward, state NOL carryforwards of approximately $9.2 million with a 20 year carryforward that starts expiring in 2043, and Australian NOL carryforwards of approximately $103.7 million with an indefinite carryforward.

At June 30, 2025, the Company had U.S. 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.

Uncertain Tax Positions

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's 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, 2026 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 2022 to 2024 in the U.S. or the Commonwealth of 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 2021 to 2024 in Australia.

Note 15. 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.

	Year Ended June 30,	
	2026	**2025**
Options to purchase common stock	115,910	91,211
Warrant to purchase common stock	1,054,381	1,054,381

Note 16. Related Party Transactions

Share Options Issued to Directors and Other Key Management Personnel

During the twelve months ended June 30, 2026, 34,559 stock options were granted to Dr. Spyros Papapetropoulos, Interim CEO, and 42,684 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 financial accounting, reporting, and Chief Financial Officer ("CFO") services 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 twelve months ended June 30, 2026, the Company paid Danforth a total of $843,714, of which $325,894 was for the service of Mr. Cunningham as our CFO. During the twelve months ended June 30, 2025, the Company paid Danforth a total of $734,648, of which $254,363 was for the service of Mr. Cunningham as our CFO.

WG Partners LLP

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 then existing agreement, the Company agreed to pay to WG Partners a monthly fee of $15,000 and applicable commissions, if any, which are subject to conditions and further addendum; however, no such commissions were earned, invoiced or paid during the twelve months ended June 30, 2026 and 2025 under the terms of this agreement.

On January 20, 2026, in connection with the Company’s previously announced initiation of a strategic evaluation process in October 2025, the Company and WG Partners entered into an amendment to the agreement to reflect WG Partners' continued services on behalf of the Company, alongside H.C. Wainwright & Co., the Company’s lead strategic alternative transaction advisor, to assist and

advise the Company in its consideration of a potential merger and acquisition, or such other strategic transaction, as the case may be. In this regard, WG Partners has extended the strategic partner outreach to territories outside of the U.S. Pursuant to the 2026 amendment, WG Partners is entitled to receive the following compensation: (i) an increase in its monthly fee from $15,000 to $20,000, plus VAT where applicable, (ii) a one-time retainer of $100,000, plus VAT where applicable, which payment was made upon entry into such 2026 amendment; and (iii) a strategic transaction success fee of $350,000, plus VAT where applicable, payable on the completion of a potential merger and acquisition transaction, if any. The agreement will continue until such time as a party gives 30 days prior written notice of termination to the other party. During the twelve months ended June 30, 2026 and 2025, WG Partners invoiced the Company for monthly stipend fees of $219,981 and $148,971, respectively.

Note 17. 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. Inputs used are based on the anticipated amounts and timing of potential milestone and royalty payments from the 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 tables detail the change in fair value of the contingent consideration liability for the periods presented:

	Contingent Consideration in a Business Combination
Balance at June 30, 2025	$ 1,169,675
Change in fair value, net of foreign currency effect	(144,374)
Balance at June 30, 2026	$ 1,025,301

	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

Note 18. 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 remaining liability in relation to severance agreements with certain employees, including Dr. Spyros Papapetropoulos, for severance pay of approximately $0.1 million at June 30, 2026 and has included said amount in the restructuring liability.

Note 19. Segment Reporting

The Company operates through a single operating and reporting 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 positioning itself for the completion of a merger transaction as announced on a. The Company manages all business activities on a consolidated basis. The Company's Chief Operating Decision Maker ("CODM") is the Interim 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 20. Subsequent Events

The Company has evaluated subsequent events through September 18, 2026 and has concluded that no events or transactions have occurred that require disclosure in the accompanying consolidated financial statements, except as follows:

Proposed Merger with Scancell

On July 23, 2026, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with Scancell Holdings plc, a public limited company incorporated under the laws of England and Wales ("Parent"), and Scancell Merger Sub, Inc., a Delaware corporation and an indirect wholly owned subsidiary of Parent ("Merger Sub"). Upon the terms and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will be merged with and into the Company, with the Company surviving the merger as an indirect wholly owned subsidiary of Parent (the "Merger" and, together with the other transactions contemplated by the Merger Agreement, the "Transactions"). All defined terms used in this summary of the Merger Agreement that are not otherwise defined herein have the meanings ascribed to such terms in the Merger Agreement.

Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger (the "Effective Time"), each share of common stock of the Company, par value $0.00001 per share ("Company Common Stock"), issued and outstanding immediately prior to the Effective Time, other than excluded shares, will be converted into the right to receive (i) a number of American Depositary Shares of Parent ("Parent ADSs") equal to the exchange ratio determined in accordance with the Merger Agreement (the "Equity Consideration") and (ii) one contingent value right (each, a "CVR" and, together with the Equity Consideration, the "Merger Consideration").

Pursuant to the Merger Agreement, the exchange ratio (the "Exchange Ratio") is calculated upon the Effective Time, on a pro forma basis and based upon the number of Parent ADSs expected to be issued in connection with the Merger and the PIPE Financing. Pre-Merger stockholders of the Company (other than Subscribers in the PIPE Financing) are expected to own approximately 11.1% of the combined company, pre-Merger shareholders of Parent will own approximately 64.9% of the combined company and the Subscribers in the PIPE Financing are expected to hold approximately 17.3% (assuming gross proceeds from the PIPE Financing of $38.6 million), in each case calculated on a fully diluted basis, using the treasury stock method, and subject to certain assumptions, including (i) the Parent Valuation of $144,612,002, (ii) the Company Valuation of $24,598,949, and (iii) the relative capitalization of Parent and the Company, as determined in accordance with the Exchange Ratio formula set forth in the Merger Agreement. The Exchange Ratio and related share counts are subject to customary anti-dilution adjustment for stock splits or similar events (including Parent's planned reverse share split) between signing and closing, and no fractional Parent ADSs will be issued, with fractional entitlements rounded to the nearest whole ADS.

The Merger Agreement contains representations and warranties of the parties regarding their respective businesses. The Merger Agreement also contains certain covenants made by each of the Company and Parent, including non-solicitation restrictions binding each party (and subject to certain exceptions as further described in the Merger Agreement) and its representatives and restrictions on the operation of each party's business between the date of the Merger Agreement and the Effective Time.

In connection with the Merger, the parties will prepare and Parent will cause to be filed with the SEC a registration statement on Form F-4, which will contain a proxy statement relating to the Company Stockholder Meeting (the "Proxy Statement/Prospectus"), to register the Parent ADSs and the Parent Ordinary Shares represented thereby to be issued pursuant to the Merger (the "Form F-4"). The Company will seek the approval of the Company's stockholders at the Company Stockholder Meeting, which will be called for the purpose of voting on the adoption of the Merger Agreement (the "Company Stockholder Approval"). In addition, Parent will seek the approval of Parent's shareholders at the Parent Shareholder Meeting, which will encompass resolutions required under the Companies Act 2006 to implement the Merger and the Concurrent Financing, including, among other matters: (i) the allotment of the Parent Consideration Shares to be issued to stockholders of the Company in connection with the Merger; (ii) the AIM Reverse Split at

a ratio to be mutually agreed upon by Parent and the Company, to be effected prior to the Closing; and (iii) the allotment of Parent Ordinary Shares and Non-Voting Ordinary Shares in connection with the Concurrent Financing (the "Parent Shareholder Approval").

In the event the Company's Board of Directors makes a Company Board Adverse Recommendation Change (as defined in the Merger Agreement) as a result of a Superior Offer (as defined in the Merger Agreement), the Company will remain obligated to hold the stockholder meeting to seek the Company vote on the Company Stockholder Approval under the terms of the Merger Agreement and may not terminate the Merger Agreement in order to enter into an agreement with respect to such Superior Offer.

The completion of the Merger is subject to customary closing conditions, including, among others, (i) the Company Stockholder Approval and the Parent Shareholder Approval; (ii) approval of the Nasdaq listing of the Parent ADSs (and the Parent Ordinary Shares represented thereby); (iii) Subscription Agreements remaining in full force and effect and Parent receiving not less than $75.0 million in gross cash proceeds from the concurrent financing prior to or substantially simultaneously with the closing; (iv) effectiveness of the Form F-4; (v) circulation of the Parent Circular to Parent's shareholders; (vi) Closing Net Cash of at least $10,000,000 as of December 31, 2026 or at the Closing, whichever occurs earlier; (vii) receipt by Parent of certain required third-party consents; and (viii) execution and delivery by the applicable signatories of the Company Lock-Up Agreements and the Parent Lock-Up Agreements, each of which shall be in full force and effect as of immediately following the Effective Time.

The Merger Agreement contains certain termination rights for the Company and Parent, including termination by mutual written agreement, by either party if the Merger has not been consummated by February 28, 2027, subject to a 60-day extension if the SEC has not declared the Form F-4 effective, by either party if a final and non-appealable governmental order permanently enjoins or prohibits the Merger, by either party if the Company stockholder approval or Parent Shareholder Approval is not obtained, by Parent in certain circumstances involving a Company adverse recommendation change or material breach of the Company's no-solicitation obligations, and by either party for certain uncured breaches by the other party.

If the Merger Agreement is terminated due to the failure to obtain the Company Stockholder Approval at the Company Stockholder Meeting, the Company may be required to pay to Parent a Company No Vote Payment, equal to Parent's aggregate fees and expenses reasonably incurred in connection with the transactions contemplated by the Merger Agreement. Similarly, if the Merger Agreement is terminated due to the failure to obtain the Parent Shareholder Approval at the Parent Shareholder Meeting, Parent may be required to pay to the Company a Parent No Vote Payment, equal to the Company's aggregate fees and expenses reasonably incurred in connection with the transactions contemplated by the Merger Agreement.

Voting and Lock-Up Agreements

Concurrently with the execution of the Merger Agreement, certain stockholders of the Company, including all directors and officers and certain other significant holders of common stock, entered into voting and support agreements with Parent and Merger Sub (the "Company Voting Agreements"). Under the Company Voting Agreements, each securityholder agreed, among other things, not to transfer covered securities or enter into voting trusts or similar arrangements with respect to covered securities, subject to customary permitted transfers, and to appear at stockholder meetings for quorum purposes and vote the covered securities in favor of the Merger Agreement and the Transactions and any related adjournment proposal, and against competing acquisition proposals and other actions, proposals, transactions or agreements that could reasonably be expected to impede, interfere with, delay, discourage, adversely affect or inhibit the timely consummation of the Transactions. Each such securityholder also granted Parent an irrevocable proxy to vote the Subject Securities (as defined below) consistent with these obligations, agreed to customary non-solicitation, confidentiality, no-litigation and further-assurances covenants, and made customary representations and warranties regarding its ownership of and authority over the Subject Securities.

The Company Voting Agreements terminate automatically upon the earliest of the Effective Time, termination of the Merger Agreement in accordance with its terms, certain amendments, waivers, supplements or changes to the Merger Agreement made without the applicable securityholder's prior written consent that decrease or change the form of consideration or otherwise materially and adversely affect such securityholder, a Company Adverse Recommendation Change, or the date and time set forth in a written agreement of Parent and the applicable securityholder.

Concurrently with the execution of the Merger Agreement, certain shareholders and all directors of Parent entered into a voting and support deed with Parent, Merger Sub and the Company (the "Parent Voting and Support Deed"), covering the ordinary shares of Parent held by such shareholder together with any additional Parent or Company securities acquired during the term of the deed (the "Subject Securities").

Under the Parent Voting and Support Deed, each securityholder agreed, among other things, not to transfer the Subject Securities or enter into voting trusts, proxies, or similar arrangements with respect to them, subject to customary permitted transfers to estate-planning or charitable transferees, affiliated entities, or other transferees who agree to be bound by the deed. Each such securityholder also agreed to appear (in person or by proxy) at Parent shareholder meetings for quorum purposes and to vote the Subject Securities in favor of the Parent Shareholder Approval and any related adjournment proposal, and against any action that could reasonably be expected to breach Parent's or each such securityholder's obligations under the Merger Agreement or the deed, and any other action, proposal, transaction or agreement that could reasonably be expected to impede, interfere with, delay, discourage, adversely affect, or

inhibit the timely consummation of the transactions or change the voting rights of Parent's shares. Each such securityholder also granted Parent an irrevocable proxy to vote the Subject Securities consistent with these obligations, agreed to customary non-solicitation, confidentiality, no-litigation and further-assurances covenants, and made customary representations and warranties regarding its ownership of and authority over the Subject Securities.

The Parent Voting and Support Deed terminates automatically upon the earliest of the Effective Time, termination of the Merger Agreement in accordance with its terms, as to a given securityholder, any amendment, waiver, supplement or change to the Merger Agreement made without that securityholder's prior written consent that materially and adversely affects such securityholder, a Parent Adverse Recommendation Change, or the date and time set forth in a written agreement between Parent and the applicable securityholder.

At the Effective Time, certain directors, officers and stockholders of the Company and Parent, are expected to enter into lock-up agreements (the "Lock-Up Agreements"). Pursuant to the Lock-Up Agreements, subject to specified exceptions, the applicable signatories are expected to accept restrictions on transfers of Parent ADSs and any Parent ordinary shares represented thereby that are beneficially owned by such persons or received in connection with the Merger for the restricted period specified in the applicable Lock-Up Agreement.

Contingent Value Rights Agreement

At or prior to the Effective Time, Parent is expected to enter into a Contingent Value Rights Agreement (the "CVR Agreement") with a rights agent (the "Rights Agent"). Pursuant to the CVR Agreement, the initial holders will be the holders of Company Common Stock as of the close of business on the last business day prior to the day on which the Effective Time occurs, and one CVR will be issued with respect to each share of Company Common Stock outstanding as of such record date.

Each CVR represents a contractual right to receive a pro rata share of CVR payments, if any, equal to 100% of the net proceeds actually received by Parent or its affiliates (i) under the Company's research collaboration and license agreement with Merck Sharp & Dohme Corp. for a period of 15 years from Completion; (ii) under the Participants Agreement and associated CRC Commercialization License Agreements (including the existing license agreement with Pfizer relating to KAT6), for a period of 15 years from Completion; (iii) pursuant to any monetization of certain of the Company's intellectual property rights within the applicable timeframe as set out in the CVR Agreement; and (iv) in respect of an Australian R&D tax credit of the Company in respect of the year ended June 30, 2026. The CVR Agreement defines gross proceeds to include upfront, milestone, royalty and other payments received under the applicable Partner Agreements (as defined in the CVR Agreement), subject to the exclusions and deductions described in the CVR Agreement. The CVRs will not be evidenced by certificates or other instruments, will not have voting or dividend rights, will not bear interest, will not represent any equity, loan capital or ownership interest in Parent or any of its affiliates and will not be listed on any quotation system or traded on any securities exchange. The CVRs will be non-transferable except through limited permitted transfers, and there can be no assurance that any CVR holder will receive any payment pursuant to the CVR Agreement.

Subscription Agreements

In connection with the Merger Agreement, Parent entered into subscription agreements (each, a "Subscription Agreement" and collectively, the "Subscription Agreements") with certain investors (each, a "Subscriber"), pursuant to which each Subscriber agreed to purchase, and Parent agreed to issue and sell, Parent ADSs and/or voting and/or non-voting ordinary shares of Parent, par value £0.001 per share (the "Ordinary Shares", "Non-Voting Ordinary Shares" and, together with the Parent ADSs, the "PIPE Securities"), at a purchase price of $0.1205 per PIPE Security (the "Placement Price"), in a private placement (the "PIPE Financing") to be consummated prior to or concurrently with the closing of the Merger. The closing of the PIPE Financing is contingent upon, and will occur on the date of, the closing of the Merger, and is subject to customary closing conditions.

Parent has agreed, within thirty (30) calendar days after the closing of the Merger, to file with the SEC a registration statement registering the resale of the PIPE Securities and to use commercially reasonable efforts to cause it to become effective as soon as practicable thereafter. Each Subscription Agreement will automatically terminate, and the related PIPE Securities will not be issued, upon the earliest of the mutual written agreement of the parties to terminate, the termination of the Merger Agreement in accordance with its terms, the failure of the applicable closing conditions to be satisfied or waived as of the closing date, or written notice of termination by either party if the transactions contemplated by the Subscription Agreement have not been consummated by the End Date.

UK Placing and Retail Offer

Concurrently with the signing of the Merger Agreement, Parent has entered into a placing agreement with Panmure Liberum Limited (the "Placing Agreement" and the "UK Placement Agent") in connection with a proposed equity raise of approximately $12.0 million (c.£9.0 million) via a placing of new Ordinary Shares via an accelerated bookbuild process with select new and existing UK institutional investors at the GBP equivalent of the Placement Price (the "UK Placing"). In addition, Parent has entered into a retail offer agreement with Winterflood, a division of Marex Financial, to conduct a retail offer (the "Retail Offer") via the Winterflood Retail Access Platform at the GBP equivalent of the Placement Price to raise up to a further $3.0 million (c. £2.3 million), open to

existing shareholders of Parent and new qualifying UK retail investors. The UK Placing and the Retail Offer will each be effected pursuant to Parent's existing share capital authorities. Neither the UK Placing nor the Retail Offer is conditional upon completion of the Merger and the PIPE Financing. The UK Placing and the Retail Offer are expected to complete, and the new Ordinary Shares will be admitted to trading on AIM, a market of the London Stock Exchange, on July 28, 2026.

Warrant Amendment Letter Agreement

On July 20, 2026, the Company entered into a letter agreement (the "Warrant Letter Agreement") with Armistice Capital Master Fund Ltd. ("Armistice"), the holder of a Common Stock Purchase Warrant issued by the Company to Armistice on June 4, 2024, and replaced following the Company's redomiciliation on December 24, 2024 (the "Warrant").

Pursuant to the Warrant Letter Agreement, the parties agreed that, if the "Black Scholes Value" (as defined in the Warrant) otherwise payable to Armistice upon exercise of the "Cash-Out Right" (as defined in the Warrant) in connection with the Merger exceeds $3,500,000, the amount of such excess (the "Excess Amount") will be payable to Armistice, at its option and in lieu of cash, in the form of Parent ordinary shares, Parent ADSs, warrant to purchase Parent ordinary shares or Parent ADSs, or a combination thereof (the "Warrant Equity Consideration"). The number of Parent ordinary shares constituting or underlying the Warrant Equity Consideration will equal the Excess Amount (or the portion thereof paid as Warrant Equity Consideration) divided by the Parent Per Share Price (as defined in the Merger Agreement), multiplied by 125%. Except as expressly modified by the Warrant Letter Agreement, all other terms and conditions of the Warrant remain unmodified and in full force and effect.

The foregoing descriptions of the Merger Agreement, the Company Voting Agreements, the Parent Voting and Support Deed, the Lock-Up Agreements, the CVR Agreement, the Subscription Agreements and the Warrant Amendment Letter Agreement are qualified in their entirety by reference to the full text of the Merger Agreement, the form of Voting Agreement, the form of Parent Voting and Support Deed, the form of Lock-Up Agreement, the form of CVR Agreement, the form of Subscription Agreement with institutional investors, the form of Subscription Agreement with individual investors and the Warrant Letter Agreement, copies or forms of which are included as Exhibits 2.3, 10.28, 10.29, 10.30, 10.31, 10.32, 10.33 and 10.34, respectively, to this Annual Report on Form 10-K and are incorporated herein by reference.

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 18, 2026 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, 2026.

/s/ WOLF & COMPANY P.C.
Boston, Massachusetts

September 18, 2026

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 18, 2026

/s/ Spyridon Papapetropoulos
Spyridon Papapetropoulos
Interim 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 18, 2026

/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, 2026 (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 18, 2026

/s/ Spyridon Papapetropoulos
Spyridon Papapetropoulos
Interim 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, 2026 (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 18, 2026

/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.