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Registration No. 333-

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

# FORM F-1
# REGISTRATION STATEMENT
***UNDER***
***THE SECURITIES ACT OF 1933***

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

**Not applicable**
**(Translation of registrant's name into English)**

| **Australia** | **2834** | **98-1008557** |
|---|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(Primary Standard Industrial Classification Code Number)** | **(I.R.S. Employer Identification No.)** |

**200 Greenhill Road**
**Eastwood SA 5063**
**Australia**
**+618 8150 7400**
**(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)**

**Errol De Souza, Ph.D.**
**Executive Chairman**
**c/o CSC-Lawyers Incorporating Service**
**2710 Gateway Oaks Drive, Suite 150N**
**Sacramento, CA 95833**
**(Name, address, including zip code, and telephone number, including area code, of agent for service)**

***Copies to:***

| **Michael E. Sullivan, Esq.** | **Anthony W. Basch, Esq.** |
|---|---|
| **Nathan Ajiashvili, Esq.** | **Yan (Natalie) Wang, Esq.** |
| **Latham & Watkins LLP** | **Kaufman & Canoles, P.C.** |
| **12670 High Bluff Drive** | **Two James Center** |
| **San Diego, California 92130** | **1021 East Cary Street, Suite 1400** |
| **(858) 523-5400** | **Richmond, VA 23219** |
| | **(804) 771-5700** |

Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933.

Emerging growth company ☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, 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 7(a)(2)(B) of the Securities Act. ☐

**The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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**The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.**

**Subject to completion dated November , 2022**

**PRELIMINARY PROSPECTUS**

# AMERICAN DEPOSITARY SHARES

# REPRESENTING ORDINARY SHARES

Bionomics

## per ADS

This is an offering of Bionomics Limited in the United States. Bionomics Limited is offering American Depositary Shares ("ADSs"), each representing ordinary shares.

Our ordinary shares are listed on the Australian Securities Exchange ("ASX"), under the symbol "BNO."

On , 2022, the closing price of our ordinary shares on the ASX was A$ per ordinary share ($ per share, based on an exchange rate of A$1.00 to $0.6889 as published by the Reserve Bank of Australia as of June 30, 2022), equivalent to $ per ADS. ADSs representing our ordinary shares are listed on the Nasdaq Global Market under the symbol "BNOX." On , 2022, the last reported sale price of the ADSs on the Nasdaq Global Market was $ per ADS.

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, are subject to reduced public company disclosure standards. See "Prospectus Summary—Implications of Being an Emerging Growth Company."

**Investing in our ADSs involves a high degree of risk. Before buying any ADSs, you should carefully read the discussion of material risks in "Risk Factors" beginning on page 13 of this prospectus.**

| | Per ADS | Total |
|---|---|---|
| Public offering price | $ | $ |
| Underwriting discounts and commissions(1) | $ | $ |
| Proceeds, before expenses, to us | $ | $ |

(1) We have agreed to reimburse the underwriters for certain expenses in connection with this offering. See "Underwriting."

We have granted the underwriters an option to purchase a maximum of additional ADSs from us within 30 days following the closing date of this offering.

Neither the Securities and Exchange Commission ("SEC") nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the ADSs to investors on or about , 2022.

**AEGIS CAPITAL CORP.** **BERENBERG**

**The date of this prospectus is , 2022.**

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We are incorporated under the laws of Australia. The majority of our directors and officers and certain other persons named in this prospectus are citizens and residents of countries other than the United States and all or a significant portion of the assets of the directors and officers and certain other persons named in this prospectus and substantially all of our assets are located outside of the United States. As a result, it may not be possible for you to effect service of process within the United States upon such persons or to enforce against them or against us in U.S. courts judgments predicated upon the civil liability provisions of the federal securities laws of the United States. There is doubt as to the enforceability in Australia, either in original actions or in actions for enforcement of judgments of U.S. courts, of civil liabilities predicated on U.S. federal securities laws.

As a foreign private issuer, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as domestic registrants whose securities are registered under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

You should rely only on the information contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We have not authorized anyone to provide you with different information. We are offering to sell, and seeking offers to buy, our ADSs only in jurisdictions where offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our ADSs. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not and the underwriters have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the ADSs and the distribution of this prospectus outside the United States.

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market share, is based on information from our own management estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable. Our management estimates have not been verified by any independent source, and we have not independently verified any third-party information. In addition, assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates. See "Special Note Regarding Forward-Looking Statements."

We use our registered and unregistered trademarks, including Bionomics™, in this prospectus. This prospectus also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this prospectus 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.

Unless otherwise indicated, all amounts presented in this prospectus are presented in U.S. Dollars ("US$"). Our reporting and functional currency is the Australian Dollar ("A$"). Solely for the convenience of the reader, this prospectus contains translations of certain Australian Dollar amounts into U.S. Dollars at specified rates. Except as otherwise stated in this prospectus, all translations from Australian Dollars to U.S. Dollars are based on the exchange rate of A$1.00 to $0.6889 as published by the Reserve Bank of Australia as of June 30, 2022. No representation is made that Australian Dollar amounts referred to in this prospectus could have been or could be converted into U.S. Dollars at such rates or any other rates. Any discrepancies in any table between totals and sums of the amounts listed are due to rounding.

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 audited consolidated financial statements and related notes included in this prospectus are presented in Australian Dollars and have been prepared in accordance with International Financial Reporting Standards ("IFRS"), and interpretations issued by the International Accounting Standards Board ("IASB").

## Prospectus Summary

*This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our ADSs. You should read this entire prospectus carefully, especially the section in this prospectus entitled "Risk Factors" beginning on page 13, "Business," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes thereto included at the end of this prospectus, before making an investment decision. As used in this prospectus, unless the context otherwise requires, references to "we," "us," "our," "our company" and "Bionomics" refer to Bionomics Limited and its consolidated subsidiaries.*

### Overview

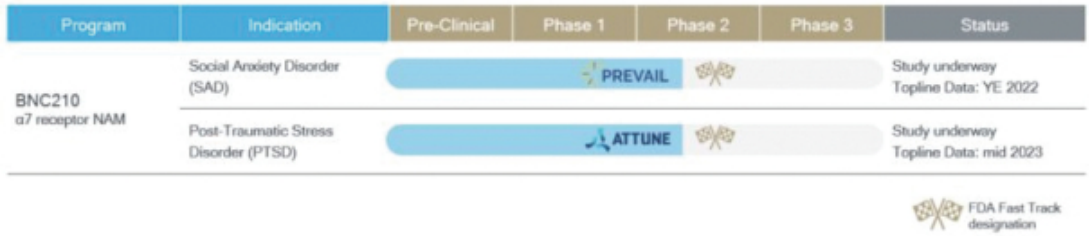
We are a clinical-stage biopharmaceutical company developing novel, allosteric ion channel modulators designed to transform the lives of patients suffering from serious central nervous system ("CNS") disorders with high unmet medical need. Ion channels serve as important mediators of physiological function 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") and positive allosteric modulators ("PAMs") of the α7 receptor to treat anxiety and stressor-related disorders and cognitive dysfunction, respectively.

We are advancing our lead product candidate, BNC210, an oral, proprietary, selective NAM of the α7 receptor, for the acute treatment of Social Anxiety Disorder ("SAD") and chronic treatment of Post-Traumatic Stress Disorder ("PTSD"). There remains a significant unmet medical need for the over 22 million patients in the United States alone suffering from SAD and PTSD. Current pharmacological treatments include certain antidepressants and benzodiazepines, and there have been no new FDA approved therapies in these indications in nearly two decades. These existing treatments have multiple shortcomings, such as a slow onset of action of antidepressants, and significant side effects of both classes of drugs. 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.

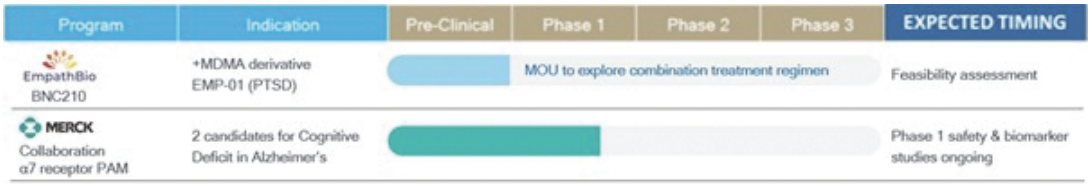
We have initiated our Phase 2 PREVAIL trial for BNC210 for the acute treatment of SAD and currently anticipate reporting topline data by the end of 2022. We have initiated our Phase 2b ATTUNE trial, a randomized, placebo-controlled study to evaluate BNC210 for the treatment of PTSD and we expect to report topline data in mid-2023. Our expertise and approach have been validated through our June 2014 research collaboration and license agreement (as amended, the "2014 Merck License Agreement") with Merck Sharp & Dohme Corp., a wholly owned subsidiary of Merck & Co., Inc., Kenilworth NJ, USA ("Merck") for our α7 receptor PAM program, which targets a receptor that has garnered significant attention for treating cognitive deficits. This partnership enables us to maximize the value of our ion channel and chemistry platforms and develop transformative medicines for patients suffering from cognitive disorders such as Alzheimer's disease.

**Our Portfolio**

Below is a summary of our non-partnered pipeline, which shows the current status and expected topline data:




Below is a summary of the status of the programs under our collaboration relationships:




*For information regarding additional programs in our portfolio, including programs under certain collaboration relationships, see "— Additional Programs".*

**BNC210**

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

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

We have administered BNC210 in approximately 400 subjects across 12 completed clinical trials, including healthy volunteers, elderly patients with agitation and patients with Generalized Anxiety Disorder ("GAD") and PTSD. We have observed BNC210 to be generally well tolerated in the trials to date following both acute and chronic dosing. Further, in our clinical trials in GAD patients and in panic-induced healthy subjects, we have observed three key results:

- statistically significant reductions in hyperactivity in the amygdala, the region of the brain responsible for emotional control, when exposed to fear-inducing triggers;

- in a head-to-head study, showed a statistically significant reduction in the intensity of defensive behavior, while lorazepam, a widely prescribed benzodiazepine did not; and
- a statistically significant reduction in the intensity and total number of panic symptoms as well as more rapid recovery from the panic state relative to placebo.

We have designed and developed a novel, proprietary tablet formulation of BNC210 which has shown differentiated pharmacokinetic properties in clinical trials. BNC210 tablet has demonstrated rapid oral absorption characteristics in clinical trials making it ideal for acute, or on demand, treatment of SAD. Furthermore, the tablet formulation is intended to provide patients the convenience of taking BNC210 with or without food in the outpatient setting. In previous clinical trials (using 900 mg twice daily dosing similar to that being used in the ATTUNE Study), the tablet formulation achieved a target blood exposure ranging from 33-57 mg.h/L, which exceeds the blood exposure of approximately 25 mg.h/L which our pharmacometric analysis predicted as likely to show clinically meaningful benefit for patients suffering from PTSD. We are using this tablet formulation in our ongoing Phase 2b ATTUNE clinical trial for patients with PTSD and Phase 2 PREVAIL trial for patients with SAD. We anticipate topline data for our SAD trial by the end of 2022 and for our PTSD trial in mid-2023. We have received Fast Track designation from the FDA for our PTSD and SAD programs. In addition, we have a memorandum of understanding with EmpathBio for preclinical feasibility studies to evaluate a combination of EMP-01, a 3,4-methylenedioxymethamphetamine (“MDMA”) derivative and BNC210 as an adjunct to behavioral therapy for the treatment of PTSD.

**Additional Programs**

***α7 Receptor PAM Program with Merck***

In June 2014, we entered into the 2014 Merck License Agreement to develop α7 receptor PAMs targeting cognitive dysfunction associated with Alzheimer’s disease and other central nervous system conditions. Under the 2014 Merck License Agreement, Merck funded certain research and development activities on a full-time equivalent (“FTE”) basis pursuant to a research plan. Merck funds current and future research and development activities, including clinical development and worldwide commercialization of any products developed from the collaboration. We received upfront payments totaling $20 million, which included funding for FTEs for the first twelve months, and another $10 million in February 2017 when the first compound from the collaboration initiated Phase 1 clinical trials, and we are eligible to receive up to an additional $465 million in milestone payments for achievement of certain development, regulatory and commercial milestones. The Merck collaboration currently includes two candidates which are PAMs of the α7 receptor that are in early-stage Phase 1 safety and biomarker clinical trials for treating cognitive impairment. The first compound has completed Phase 1 safety clinical trials in healthy subjects and there are ongoing biomarker studies. In 2020, a second molecule that showed an improved potency profile in preclinical animal models was advanced by Merck into Phase 1 clinical trials. Merck controls the clinical development and worldwide commercialization of any products developed from the collaboration and therefore we cannot predict whether or when we might achieve any milestone payments under the collaboration or estimate the full amount of such payments, and we may never receive any such payments. Further, we are subject to limited information rights under the 2014 Merck License Agreement. As such, we are dependent on Merck to provide us with any updates related to clinical trial results, serious adverse events and ongoing communications with FDA or other regulatory agencies related to these programs, which Merck may provide or withhold in its sole discretion, and as a result we may not be able to provide material updates on a timely basis or at all with respect to these programs.

***Our Early-Stage CNS Assets***

Our CNS pipeline includes two earlier stage small molecule discovery programs targeting ion channels and represents additional opportunities for future clinical programs and partnering. These programs are at a similar stage to the stage at which the α7 receptor PAM program was licensed under the 2014 Merck License Agreement,

although there is no assurance that we will be able to enter into a license or collaboration agreement with respect to these programs. The first of these programs has developed two patented series of small molecule Kv3.1/3.2 potassium channel activators for the potential treatment of cognitive deficits and negative symptoms/social withdrawal in schizophrenia and autism spectrum disorders. The second program has developed three patented series of small molecule inhibitors with functional selectivity for Nav1.7 and Nav1.8 voltage gated sodium ion channels for the potential treatment of chronic pain without the liability of addiction associated with opioid treatment.

***Legacy Oncology Programs***

We have a portfolio of legacy clinical-stage oncology programs targeting cancer stem cells (BNC101) and tumor vasculature (BNC105) that we have progressed through external funding for clinical trials and out-licensing to capture future value for our shareholders. Our first legacy oncology program is BNC101, a novel humanized monoclonal antibody that targets LGR5, a cancer stem cell receptor highly overexpressed in most solid tumors. In November 2020, we exclusively licensed BNC101 to Carina Biotech for the development of chimeric receptor antigen T-cell ("CAR-T") therapeutics in return for milestones and royalties. Our second legacy oncology program, BNC105, is a novel vascular tubulin polymerization inhibitor agent for treatment of cancer, which disrupts the blood vessels that nourish tumors. We plan to advance these oncology programs only through existing and potentially new partnerships.

**Our Team**

We have assembled a strong management team of experts complemented by an international board of directors with deep scientific and clinical expertise in CNS drug discovery and development and expertise in strategy and business development. The management team is led by Errol B. De Souza, Ph.D., our Executive Chairman, who has over 30 years of substantive experience as an executive in the biopharmaceutical industry, having founded Neurocrine Biosciences, served as President and CEO of several U.S.-based public and private biopharmaceutical companies including Biodel, Synaptic Pharmaceutical Corp., Archemix and Neuropore Therapeutics, and led large Research & Development organizations (Head of CNS Diseases at DuPont Merck and Head of US R&D at Aventis Pharmaceuticals) in global pharmaceutical companies. We have assembled an experienced management and scientific team with a track record of success in the field of CNS drug development. Members of our management team have held senior positions at Deloitte Touche Tohmatsu, New World Bio Limited, Apeiron Investment Group, Circumvent Pharmaceuticals and RBC Capital Markets. We believe that the breadth of experience and successful track record of our senior management, combined with our established relationships with leaders in the industry and medical community, provide us with unique insights into drug development for the treatment of CNS disorders. We have also been supported by a leading syndicate of investors, including BVF Partners L.P. ("BVF") and Apeiron Investment Group Ltd.

**Our Strategy**

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

- Advance our lead product candidate, BNC210, through clinical development and to commercialization, if approved, for the acute treatment of patients with SAD.
- Progress BNC210 through clinical development and to commercialization, if approved, in patients with PTSD.
- Expand indication potential for BNC210 to other acute and chronic anxiety and stressor-related disorders.

- Build a commercialization infrastructure in the United States for BNC210.
- Maximize the potential of our CNS programs and legacy oncology assets through selective partnerships and licensing.
- Continue to strategically expand our clinical pipeline through acquisitions, licenses, and/or collaborations.

**Risks Factors**

You should carefully consider the risks described in the section entitled "Risk Factors" immediately following this prospectus summary. These risks include, among others:

- 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.
- Even if this offering is successful, 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.
- Preclinical and clinical drug development is a lengthy and expensive process, with an uncertain outcome. Our preclinical and clinical programs may experience delays or may never advance, which would 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.
- 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.
- The trading price of our ordinary shares has been volatile, and that of our ADSs may be volatile, and you may not be able to resell the ADSs at or above the price you paid.
- An active trading market for the ADSs may not be maintained or be liquid enough for you to sell your ADSs quickly or at market price.
- Your right as a holder of ADSs to participate in any future preferential subscription rights offering or to elect to receive dividends in ordinary shares may be limited, which may cause dilution to your holdings.
- 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.
- We may have difficulties in attracting and retaining key personnel, and if we fail to do so our business may suffer.
- We depend on collaboration partners to develop and commercialize our collaboration product candidates, including Merck and Carina Biotech. If our collaboration partners fail to perform as expected, fail to advance our collaboration product candidates or are unable to obtain the required regulatory approvals for our collaboration product candidates, the potential for us to generate future revenue from such product candidates would be significantly reduced and our business would be significantly harmed.
- We currently rely, and expect to continue to rely, on third parties to conduct some or all aspects of our product manufacturing, research and preclinical and clinical testing, and these third parties may not perform satisfactorily.

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

**Corporate Information**

Bionomics Limited is an Australian public company incorporated in 1996 and listed on the Australian Securities Exchange ("ASX") since 1999. Our registered office is located at 200 Greenhill Road Eastwood SA 5063 Australia, and our telephone number is +61 8 8150 7400. Our agent for service of process in the United States is c/o CSC-Lawyers Incorporating Service, 2710 Gateway Oaks Drive, Suite 150N, Sacramento, CA 95833. Our website address is *www.bionomics.com.au.* The information contained in, or accessible through, our website does not constitute part of this prospectus.

**Implications of Being an Emerging Growth Company**

As a company with less than $1.235 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"), enacted in April 2012. An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act");
- reduced disclosure obligations regarding executive compensation in our periodic reports (if any), proxy statements (if any) and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of our initial public offering ("IPO"). However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.235 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in this prospectus and in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information in this prospectus and that we provide to our stockholders in the future may be different than what you might receive from other public reporting companies in which you hold equity interests.

**Implications of Being a Foreign Private Issuer**

We are also considered a "foreign private issuer" as defined in Rule 405 under the Securities Act of 1933, as amended (the "Securities Act"). In our capacity as a foreign private issuer, we are exempt from certain rules under the Exchange Act that impose certain disclosure obligations and procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and the rules under the Exchange Act with respect to their purchases and sales of our ordinary shares. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. In addition, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information.

We may take advantage of these exemptions until such time as we are no longer foreign private issuer. We would cease to be a foreign private issuer at such time as more than 50% of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: (1) the majority of our executive officers or directors are U.S. citizens or residents, (2) more than 50% of our assets are located in the United States or (3) our business is administered principally in the United States.

As a foreign private issuer, we have taken advantage of certain reduced disclosure and other requirements in this prospectus and may elect to take advantage of other reduced reporting requirements in future filings. Accordingly, the information contained herein or that we provide shareholders may be different than the information you receive from other public companies in which you hold equity securities.

| The Offering | |
|---|---|
| ADSs offered by us | ADSs |
| ADSs to be outstanding immediately after this offering | ADSs |
| Ordinary shares to be outstanding immediately after this offering, including shares underlying ADSs | ordinary shares |
| Option to purchase additional ADSs | The underwriters have an option for a period of 30 days to purchase up to additional ADSs. |
| The ADSs | Each ADS represents ordinary shares.<br><br>The depositary (as identified below) will be the holder of the ordinary shares underlying the ADSs and you will have the rights of an ADS holder as provided in the deposit agreement among us, the depositary and holders and beneficial owners of ADSs from time to time.<br><br>You may surrender your ADSs to the depositary to withdraw the ordinary shares underlying your ADSs. The depositary will charge you a fee for such an exchange.<br><br>We may amend or terminate the deposit agreement for any reason without your consent. Any amendment that imposes or increases fees or charges or which materially prejudices any substantial existing right you have as an ADS holder will not become effective as to outstanding ADSs until 30 days after notice of the amendment is given to ADS holders. If an amendment becomes effective, you will be bound by the deposit agreement as amended if you continue to hold your ADSs.<br><br>To better understand the terms of the ADSs, you should carefully read the section in this prospectus entitled “Description of American Depositary Shares.” We also encourage you to read the deposit agreement, which will be filed as an exhibit to the registration statement to which this prospectus forms a part. |
| Depositary | Citibank, N.A. |
| Use of proceeds | We estimate that the net proceeds from this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately $ million, or approximately $ million if the underwriters exercise their option to purchase additional ADSs from us in full, assuming a public offering price of $ per ADS, which was the last reported sale price of our ADSs on the Nasdaq Global Market on , 2022). |

| | |
|---|---|
| | We intend to use the net proceeds from this offering along with our existing cash and cash equivalents (i) for the continued development of BNC210 for the acute treatment of SAD, including the completion of the Phase 2 PREVAIL clinical trial; (ii) for the continued development of BNC210 for the treatment of PTSD, including completion of the ongoing Phase 2b ATTUNE clinical trial; (iii) for the completion of chemistry, manufacturing and controls, long term safety and non-clinical pharmacology studies necessary to support Phase 3 pivotal trials of BNC210 for the treatment of SAD and PTSD; and (iv) for working capital and other research and development and general corporate purposes. See "Use of Proceeds" for a more complete description of the intended use of proceeds from this offering. |
| Risk factors | You should read the "Risk Factors" section of this prospectus and the other information in this prospectus for a discussion of factors to consider carefully before deciding to invest in our ADSs. |
| Lock-ups | Our directors, executive officers, employees and shareholders holding at least ten percent (10%) of the outstanding ordinary shares have agreed with the underwriters not to offer for sale, issue, sell, contract to sell, pledge or otherwise dispose of any of our ordinary shares or securities convertible into ordinary shares for a period of 60 days after the closing date of this offering. We have agreed not to issue any ordinary shares or securities convertible into ordinary shares, subject to certain exceptions, for a period of 60 days after the closing date of this offering without the consent of the underwriters. (See "Underwriting.") |
| Listing | Our ADSs are listed on the Nasdaq Global Market under the symbol "BNOX." Our ordinary shares are listed on the ASX under the symbol "BNO." |

The number of ordinary shares (including ordinary shares represented by ADSs) to be outstanding after this offering set forth above is based on 1,353,350,744 ordinary shares outstanding as of June 30, 2022, and excludes:

- 79,056,617 ordinary shares issuable upon exercise of options outstanding as of June 30, 2022, at a weighted average exercise price of A$0.164 ($0.11) per share, of which options to purchase 31,065,275 ordinary shares were vested at a weighted average exercise price of A$0.14 ($0.04) per share; and
- 142,000,000 ordinary shares issuable upon exercise of warrants outstanding as of June 30, 2022 at a weighted average exercise price of A$0.06 ($0.04) per share, of which warrants to purchase 142,000,000 ordinary shares were vested at a weighted average exercise price of A$0.06 ($0.04) per share.

In addition, the number of ordinary shares outstanding after this offering does not include shares issuable pursuant to future awards granted to our employees under our Employee Equity Plan—Plan Rules, as amended from time to time (the "Employee Equity Plan"), or that might be granted to our directors. Under the ASX Listing Rules, we cannot, without the approval of our shareholders, subject to specified exceptions, issue, during any 12 month period, any equity securities, or other securities with rights to convert into equity, if the number of those securities exceeds 15% of the number of shares on issue at the commencement of that 12 month period (or

25% if shareholder approval is obtained at our annual general meeting. See “Description of Share Capital--No Shareholder Approval of Offering”) (“Placement Capacity”). Under ASX Listing Rules, we can issue up to 100.0 million ordinary shares or 10% of the ordinary shares outstanding at the completion of our IPO to employees under the Employee Equity Plan without reducing our Placement Capacity due to a shareholder approval obtained at our 2021 Annual General Meeting. Awards to our employees above such threshold under the Employee Equity Plan would reduce our Placement Capacity in the year in which such awards are granted. Awards under the Employee Equity Plan may be issued as ADSs based on the applicable ratio of ordinary shares to ADSs.

Unless otherwise indicated, this prospectus reflects and assumes no exercise by the underwriters of their option to purchase additional ADSs.

## Summary Consolidated Financial Data

The following tables set forth a summary of our consolidated historical financial data as of, and for the periods ended on, the dates indicated. We have derived the statement of profit or loss data and the statement of financial position data for the years ended June 30, 2022 and 2021 from our audited consolidated financial statements included elsewhere in this prospectus. Our audited consolidated financial statements have been prepared in Australian Dollars and in accordance with International Financial Reporting Standards and interpretations issued by the International Accounting Standards Board. You should read this data together with our audited consolidated financial statements and related notes included elsewhere in this prospectus and the section in this prospectus entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results for any prior period are not indicative of our future results.

**Statement of Profit or Loss Data:**

| | Fiscal Year Ended June 30, | | |
|---|---|---|---|
| | 2022 | | 2021 |
| | $(1) | A$ | A$ |
| | (in thousands, except per share data) | | |
| Continuing operations: | | | |
| Revenue | $ 181 | $ 263 | $ — |
| Other income | 4,001 | 5,808 | 1,308 |
| Other gains and losses | (401) | (582) | 4,273 |
| Expenses | (18,903) | (27,440) | (14,465) |
| Loss before tax from continuing operations | (15,122) | $(21,951) | $ (8,884) |
| Income tax benefit (expense) | 132 | 192 | 187 |
| Loss after tax from continuing operations | (14,990) | $(21,759) | $ (8,697) |
| Discontinued operations: | | | |
| Loss for the year from discontinued operations | — | — | — |
| Loss for the year | (14,990) | (21,759) | (8,697) |
| Other comprehensive income: | | | |
| Exchange differences on translation of foreign operations | 735 | 1,067 | (1,169) |
| Total comprehensive profit (loss) attributable to the owners of the company | (14,255) | (20,692) | (9,866) |
| Earnings per share from continuing operations attributable to the owners of the company: | | | |
| Earnings per share, basic and diluted[2] | $ (0.01) | $ (0.02) | $ (0.01) |

**Statement of Financial Position Data:**

| | As of June 30, | | |
|---|---|---|---|
| | 2022 | | 2021 |
| | $(1) | A$ | A$ |
| | | (in thousands) | |
| Cash and cash equivalents | $23,123 | $33,565 | $28,499 |
| Trade and other receivables | 4,674 | 6,720 | 928 |
| Other current assets | 1,006 | 1,525 | 1,500 |
| Total current assets | 28,803 | 41,810 | 30,927 |
| Intangible assets and goodwill | 15,642 | 22,706 | 22,347 |
| Other non-current assets | 547 | 794 | 989 |
| Total non-current assets | 16,189 | 23,500 | 23,336 |
| Total assets | 44,992 | 65,310 | 54,263 |
| Total current liabilities | 2,312 | 3,356 | 2,361 |
| Total non-current liabilities | 3,473 | 5,042 | 4,305 |
| Total liabilities | 5,785 | 8,397 | 6,667 |
| Total equity attributable to owners of the company | 39,207 | 56,913 | 47,598 |

(1) The amounts have been translated into U.S. Dollars from Australian Dollars based upon the exchange rate as published by the Reserve Bank of Australia as of June 30, 2022. These translations are merely for the convenience of the reader and should not be construed as representations that the Australian Dollar amounts actually represent such U.S. Dollar amounts or could be converted into U.S. Dollars at such rate.

(2) See Note 2 to our audited consolidated financial statements included within our Annual Report on Form 20-F for the fiscal year ended June 30, 2022, which is incorporated by reference in this prospectus, for an explanation of the method used to compute basic and diluted earnings per share.

**Preliminary Financial Information**

As of September 30, 2022, we had A$31.4 million in cash and cash equivalents. For the three months ended September 30, 2022, we had;

- net cash used in operating activites of $3.2 million, with payments for research and development of A$3.5 million and others costs of A$1.9 million, offset by receipt of A$2.1 million for research and development tax incentive from the Australian Government and interest income of A$7 thousand; and
- net cash used in financing activites of A$0.04 million for the principal element of lease payments.

This preliminary financial information has not been audited. These results could change as a result of further review.

## Risk Factors

*Investing in our ADSs involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this prospectus, including our financial statements and related notes included elsewhere in this prospectus, before making an investment decision. If any of the following risks is realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the trading price of our ADSs could decline and you could lose part or all of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.*

### Risks Related to Our Financial Condition and Capital Requirements

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

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical company and commenced operations in 1996. To date, we have focused primarily on performing research and development activities, establishing our intellectual property portfolio (including acquisitions, in-licensing and out-licensing), discovering potential product candidates, conducting preclinical studies and clinical trials and raising capital. Our approach to the discovery and development of product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value. Our lead CNS product candidate, BNC210, is in clinical development, and our additional wholly owned CNS development programs remain in the preclinical or discovery stage. There is no guarantee that we will be able to continue the development of or advance any product candidate into further clinical trials, including to meet the capital requirements for 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, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

We have incurred significant operating losses since our inception. If our product candidates are not successfully developed and approved, we may never generate any revenue. Our total comprehensive losses were A$154.0 million ($113 million) and A$173.3 million ($119.4 million) for the fiscal years ended June 30, 2021 and 2022, respectively. As of June 30, 2022, we had net assets of A$56.9 million ($39.2 million). Substantially all of 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 product sales. 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 failto become and remain profitable, the value of our ADSs 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 of the value of our ADSs could be lost.

***Even if this offering is successful, 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 net proceeds from this offering, together with our cash and cash equivalents, will not be sufficient for us to fund all of our product candidtes through regulatory approval, and we will need to raise additional capital to complete the development and commercialization of all of our product candidates.***

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 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 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 alternative sources of financing when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We had cash and cash equivalents of A$33.6 million ($23.1 million) as of June 30, 2022. We estimate that the net proceeds from this offering will be $ , based on the closing price of $ per ADS as of , 2022, after deducting underwriting discounts and commissions and offering expenses payable by us. We believe that our existing cash and cash equivalents and the net proceeds from this offering will be sufficient to meet our anticipated cash and capital expenditure requirements through the fiscal year ending June 30, 2023. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other capital sources, including potentially collaborations, licenses and other similar 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 impact of the COVID-19 pandemic on the capital markets may affect the availability, amount and type of financing available to us in the future. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates.

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

- the type, number, scope, progress, expansions, results, costs and timing of our clinical trials (especially if and as we move into Phase 3 clinical trials) and preclinical studies of our product candidates which we are pursuing or may choose to pursue in the future;
- safety concerns related to the use of our product candidates;
- adverse findings regarding the efficacy of our product candidates as additional information is acquired;
- the costs and timing of manufacturing for our product candidates, including commercial manufacturing if any product candidate is approved;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of jurisdictions in which we plan to seek regulatory approvals;
- the costs of obtaining, maintaining, enforcing and defending our patents and other intellectual property and proprietary rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a U.S. public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our clinical activities increase;
- the timing and amount of the royalty or other payments we must make to the licensors and other third parties;
- the timing and amount of milestone or royalty payments we receive from out-licensees, such as Merck & Co., Inc., Kenliworth NJ, USA ("Merck"), Australian Cooperative Research Centre for Cancer Therapeutics ("CTx") or Carina Biotech;
- 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 would 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 purchasers of the ADSs in this offering, restrict our operations or require us to relinquish rights to our technologies or product candidates.***

Until such time, if ever, as we can generate substantial revenues, we expect to finance our business and operational needs through equity offerings, debt financings or other financing sources, including potentially

collaborations, licenses and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our ADSs. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through future collaborations, licenses and other similar arrangements, we may have to relinquish valuable rights to our future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our ADSs. 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.

***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 and development activities relating to our product candidates;
- 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 warrants and options;
- foreign currency fluctuations; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our operating results. As a result, comparisons of our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of future performance. This variability and

unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any guidelines we may provide to the market, or if the guidelines we provide to the market are below the expectations of analysts or investors, this could adversely affect the trading price of our ADSs. Such a decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

***We are entitled to research and development incentives from the Australian Government. If we lose these research and development incentives, we may encounter difficulties in funding future research and development projects, which could harm our operating results.***

We have historically received entitlements 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 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, 2021 and 2022, we recognized a refundable tax offset of approximately A$0.9 million and A$5.8 million, respectively. Entitlement to tax offsets under the Research and Development Tax Incentive for eligible research and development purposes is based on an annual application to the Australian Government. For overseas activities that have a significant scientific link to the Australian activities, the expenditure in Australia needs to be greater than the expected overseas expenditure to be eligible.

Payments under this program are available for our research and development activities in Australia, as well as certain activities conducted overseas that are required to be approved by AusIndustry, a branch of the Australian Government. In June 2021, we submitted an application to AusIndustry to seek approval of our current overseas activities relating to BNC210 as eligible expenditure under this program. On September 8, 2021, AusIndustry informed us that they would not be approving our application for our current overseas activities relating to BNC210. On October 6, 2021, we lodged a request to AusIndustry for internal review of the findings decision on our application. On October 13, 2022 AusIndustry informed us that they would conduct an internal review of the findings decision. On June 6, 2022 AusIndustry informed us that the initial decision had been overturned and our application to AusIndustry to seek approval of our current overseas activities relating to BNC210 as eligible expenditure under this program was approved. On June 14, 2022 we lodged our tax return for the fiscal year ended June 30, 2021, which incorporated the research and development tax incentive schedule, and on August 5, 2022, we received approximately $2 million the research and development tax incentive refund relating to the financial year ended June 30, 2021, which as at June 30, 2022 is included as part of the Research and Development Incentives Receivable, in the Consolidated Statement of Financial Position. In the event of our research and development expenditures being deemed "ineligible," then our incentives would decrease, and our future cash flows would be negatively affected. In addition, the Australian Government may modify the requirements of, reduce the amounts of the tax offset entitlement under, or discontinue the Research and Development Tax Incentive program. If the Research and Development Tax Incentive program was discontinued, or if the tax incentive rate was reduced, it would have a negative effect on the size of future refundable tax offsets and our future cash flows.

***We plan to use our tax losses to offset potential future taxable income from revenue generated from operations or corporate collaborations. However, our ability to utilize our tax losses and certain other tax attributes may be limited as a result of our failure to pass either the continuity of ownership or business continuity tests.***

We have substantial carried forward tax losses, which may not be available to offset future gains, if any. In order for an Australian corporate tax payor to carry forward and utilize tax losses, the taxpayor 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, including changes resulting from this offering, 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, 2022 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 has been relatively low in recent years, during 2021 and 2022, the economy in the United States encountered a material level of inflation. The impact of COVID-19, geopolitical developments such as the Russia-Ukraine conflict and global supply chain disruptions continue to increase uncertainty in the outlook of near-term and long-term economic activity, including 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 on reasonable terms may adversely impact our financial condition. Additionally, increases in inflation, along with the uncertainties surrounding COVID-19, geopolitical developments and global supply chain disruptions, have caused, and may in the future cause, global economic uncertainty and uncertainty about the interest rate environment. A failure to adequately respond to these risks could have a material adverse impact on our financial condition, results of operations or cash flows**.**

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

***Preclinical and clinical drug development is a lengthy and expensive process, with an uncertain outcome. Our preclinical and clinical programs may experience delays, unforeseen costs or may never advance, which would 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.***

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

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

- timely completion of preclinical laboratory tests, animal studies and formulation studies in accordance with FDA's good laboratory practice requirements and other applicable regulations;
- submission of an Investigational New Drug Application ("IND") to the FDA and clearance thereof by the FDA;
- approval by an independent Institutional Review Board ("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 clinical 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 obtaining required ethics committee or institutional review board ("IRB") approval at each clinical trial site;
- 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 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, including as a result of delays or difficulties due to the COVID-19 pandemic;
- 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 deviating from trial protocol or 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 of clinical studies;
- 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 countriesfor our product candidates, as in our ongoing clinical trials, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to the clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

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

***We are early in our development efforts. If we are unable to commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.***

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

- our ability to timely and successfully complete preclinical studies and clinical trials for BNC210 and other current or future product candidates;
- the ability of our existing or future licensees and collaborators to successfully develop and commercialize product candidates pursuant to collaboration agreements, including Merck with respect to its two product candidates and Carina Biotech 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 New Drug applications (“NDA”) to the FDA for BNC210 and future product candidates;
- our ability to obtain in a timely manner necessary approvals or authorizations from applicable regulatory authorities;
- the costs associated with the development of any additional development programs we identify in-house or acquire through collaborations or other arrangements;
- our ability to establish manufacturing capabilities or make arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- our ability to advance our early-stage CNS assets into IND-enabling studies either on our own or through collaborations;

- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our current and future product candidates;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- obtaining and maintaining acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement;
- the terms and timing of any additional collaboration, license or other arrangement, including the terms and timing of any payments thereunder;
- our ability to enforce and defend intellectual property rights and claims; and
- our ability to maintain continued acceptable safety profiles of our product candidates following approval.

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

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

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

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

Patient enrollment for any of our current or 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 ongoing or future clinical trials due to the COVID-19 pandemic;
- ability to obtain and maintain patient consents;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

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

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

From time to time, we may publicly disclose interim, topline or preliminary data from our preclinical studies and clinical trials, which is 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. Moreover, favorable results in earlier preclinical studies or clinical trials do not necessarily predict favorable results in subsequent studies or trials.

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

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

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

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

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

Undesirable side effects caused by our current or future product candidates could cause us to interrupt, delay or halt preclinical studies or could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other

regulatory authorities for such products. It is likely that there may be adverse side effects associated with the use of our product candidates. To date, patients treated with BNC210 have experienced drug-related side effects including headaches, somnolence and nausea. There is also the potential risk of delayed adverse events following treatment using any of our current or future product candidates.

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

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

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

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

- regulatory authorities may suspend, withdraw or limit approvals of such current or future product candidates, or seek an injunction against their manufacture or distribution;
- regulatory authorities may require the addition of labeling statements or warnings, such as “boxed” warnings 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 seek and fail to obtain Breakthrough Therapy designation or Fast Track designation from the FDA for our current or future product candidates. Even if granted for any of our current or future product candidates, these programs may not lead to a faster development, regulatory review or approval process, and such designations do not increase the likelihood that any of our product candidates will receive marketing approval in the U.S.***

We have obtained a Fast Track designation for BNC210 for the treatment of PTSD and other trauma-related and stressor-related disorders as well as for the acute treatment of anxiety in SAD patients and other anxiety-related disorders and may seek Breakthrough Therapy designations. 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. 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.

***The incidence and prevalence for target patient populations of our product candidates have not been established with precision. If the market opportunities for our product candidates in SAD, PTSD, or other indications we may pursue are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability will be adversely affected, possibly materially.***

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

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

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

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance during remediation;
- revisions to the labeling, including limitation on approved uses or the addition of warnings, contraindications, or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;

- fines, warning or untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or withdrawal of approvals;
- product seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil or criminal penalties.

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

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our current or future product candidates. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

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

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

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

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

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

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

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

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products, and on March 18, 2020 the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. Additionally, on April 15, 2021, the FDA began conducting voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities in circumstances where the FDA determines that such remote evaluation would be appropriate based on mission needs and travel limitations. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and 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 as it adapts to the evolving COVID-19 pandemic. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a U.S. public company, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

We have conducted and may in the future choose to conduct one or more of our clinical trials outside the United States, including in Australia, New Zealand, Singapore, France and the United Kingdom. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or applicable foreign regulatory authority may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless the following are true: (i) the data are applicable

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

***The use of BNC210 with 3,4-methylenedioxymethamphetamine ("MDMA") or EMP-01, an MDMA derivative, may generate public controversy. Adverse publicity or public perception regarding MDMA may negatively influence the success of any such combination therapy.***

Therapies containing controlled substances may generate public controversy. Opponents of these therapies may seek restrictions on marketing and withdrawal of any regulatory approvals. In addition, these opponents may seek to generate negative publicity in an effort to persuade the medical community to reject these therapies. For example, we have a memorandum of understanding with EmpathBio Inc. ("EmpathBio") to conduct preclinical feasibility studies to evaluate a combination of EMP-01, an MDMA derivative, and BNC210 as an adjunct to behavioral therapy for the treatment of PTSD. As a result, we may face media-communicated criticism directed at the use of BNC210 with EMP-01. Adverse publicity from MDMA misuse may adversely affect the commercial success or market penetration achievable by any combination therapy of BNC210 and EMP-01. Anti-psychedelic protests have historically occurred and may occur in the future and generate media coverage. Political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict the introduction and marketing of any therapeutic candidates that are used in combination with MDMA or an MDMA derivative.

***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 have ongoing Phase 2 clinical trials of BNC210 for PTSD and SAD.

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

***We may have difficulties in attracting and retaining key personnel, and if we fail to do so our business may suffer.***

We are highly dependent on the members of our senior management and scientific staff, particularly our Executive Chairman, Dr. Errol De Souza, who is 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 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. Further, because we are located in Australia and may seek to retain employees in the United States, we may have additional difficulties attracting personnel to work intercontinentally.

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

***Our information technology 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 information technology systems and those of our third-party CROs and other contractors and consultants are vulnerable to attack and damage from computer viruses and malware (e.g. ransomware), malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. 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. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe we have experienced any significant system failure, accident or security breach to date, if such an event were to occur, it could result in a material disruption of our programs. For example, the loss of clinical trial data from completed or 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.

Our existing general liability and cyber liability insurance policies may not cover, or may cover only a portion of, any potential claims related to security breaches to which we are exposed or may not be adequate to indemnify us for all or any portion of liabilities that may be imposed. We also cannot be certain that our existing insurance coverage will continue to be available on acceptable terms or in amounts sufficient to cover the potentially significant losses that may result from a security incident or breach or that the insurer will not deny coverage of any future claim. Accordingly, if our cybersecurity measures, and those of our service providers, fail to protect against unauthorized access, attacks (which may include sophisticated cyberattacks) and the mishandling of data by our employees and third-party service providers, then our reputation, business, results of operations and financial condition could be adversely affected.

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

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

- different regulatory requirements for product and biologics approvals in foreign countries;
- differing U.S. and non-U.S. drug import and export rules;
- reduced protection for intellectual property rights in foreign countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- different reimbursement systems, and different competitive drugs and biologics;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- potential liability resulting from development work conducted by distributors; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters.

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

From time to time, we may pursue strategic transactions, such as acquisitions of companies, asset purchases, and in-licensing or out-licensing of drugs, product candidates or technologies. For example, in September 2012,

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

- upfront, milestone and royalty payments, equity investments and financial support of new research and development candidates including increase of personnel, all of which may be substantial;
- exposure to unknown liabilities, including potential indemnification claims from a potential spin-off or out-license of certain of our intellectual property rights;
- disruption of our business and diversion of our management's time and attention in order to develop acquired drugs, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher-than-expected acquisition and integration costs;
- lower-than-expected benefits from out-licensing or selling our technology, intellectual property or any of our subsidiaries;
- write-downs of assets or goodwill or impairment charges;
- difficulty and cost in combining or separating the operations and personnel of any acquired or sold businesses with our existing operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired or sold businesses due to changes in our senior management and ownership; and
- inability to retain key employees of any acquired businesses.

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

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

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

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

- side effects or adverse events in study participants presenting an unacceptable safety risk;

- inability to reach agreements with prospective third-party CROs and clinical trial sites, or the breach of such agreements;
- failure of third-party contractors, such as third-party CROs, or investigators to comply with regulatory requirements;
- delay or failure in obtaining the necessary approvals from regulators or IRBs or ethics committees in order to commence a clinical trial at a prospective trial site, or their suspension or termination of a clinical trial once commenced;
- a requirement to undertake and complete additional preclinical studies to generate data required to support the submission of an NDA or a Biologics License Application ("BLA");
- difficulty in having patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- problems with Active Pharmaceutical Ingredient ("API") or drug product stability or shelf-life, storage and distribution;
- adding new clinical trial sites;
- our inability to manufacture, or obtain from third parties, adequate supply of API or drug product to complete our preclinical studies and clinical trials;
- the impact of the COVID-19 pandemic on our current or 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 of the institutions in which such trial is being conducted, by any data safety monitoring board for such trial, or by the ethics committees, FDA or other regulatory authorities. Such authorities may impose a suspension or termination due to a number of factors, including: failure to conduct the clinical trial in accordance with regulatory requirements, such as the current GCPs, or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, product candidate manufacturing problems, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, delays can occur due to safety concerns arising from trials or other clinical data regarding another company's product candidate in the same compound class as one of ours.

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

If we or our collaborators experience delays in the completion of, or termination of, any clinical trial of one of our product candidates, the commercial prospects of the product candidate will be harmed, the patent protection period during which we may have the exclusive right to commercialize our drugs could be shortened and our or our collaborators' ability to commence sales and generate revenue from the drug will be delayed. In

addition, any delays in completing our clinical trials will increase our costs and slow down our product candidate development and approval process. Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

**Risks Related to Our Reliance on Third Parties**

***We depend on collaboration partners to develop and commercialize our collaboration product candidates, including Merck. 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.***

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

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

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

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

- our collaboration partners may choose not to develop and commercialize our collaboration product candidates in certain relevant markets;
- our collaboration partners may take considerably more time advancing our product candidates through the clinical and regulatory process than we currently anticipate, which could materially delay the achievement of milestones and, consequently the receipt of milestone payments from our collaboration partners;
- our collaboration partners may not inform us regarding the progress of compounds, including but not limited to whether a decision is made to advance certain compounds;
- our collaboration partners have substantial discretion under their respective agreements regarding how they structure their efforts and allocate resources to fulfil their obligations to diligently develop, manufacture, obtain regulatory approval for and commercialize our collaboration drugs;
- our collaboration partners control all aspects of commercialization efforts under their respective collaboration and license agreements and may change the focus of their development and commercialization efforts or pursue higher-priority programs and, accordingly, reduce the efforts and resources allocated to their collaborations with us;
- our collaboration partners may not pursue all indications eligible for milestones;
- our collaboration partners are solely responsible for obtaining and maintaining all regulatory approvals and may fail to develop a commercially viable formulation or manufacturing process for our product candidates, and may fail to manufacture or supply sufficient drug product for commercial use, if approved, which could result in lost revenue;
- our collaboration partners may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements;
- if any of our agreements with our collaboration partners terminate, we will no longer have any rights to receive potential revenue under such agreement, in which case we would need to identify alternative means to continue the development, manufacture and commercialization of the affected product candidates, alone or with others;
- our collaboration may have to license other patents to enable marketing of compound, and our royalties may be reduced;
- our collaboration partners have the discretion to sublicense their rights with respect to our collaboration technology in connection with collaboration product candidates to one or more third parties without our consent;
- our collaboration partners may be pursuing alternative technologies or developing alternative drugs, either on their own or in collaboration with others, that may be competitive with drugs on which they are collaborating with us or which could affect our collaboration partners' commitment to the collaboration; and
- if our collaboration partners receive approval for any of the collaboration product candidates, reductions in marketing or sales efforts or a discontinuation of marketing or sales of our product candidates by our collaboration partners would reduce any milestones and royalties we could be entitled to receive.

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

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

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

We may seek to advance the development and commercialization of our unpartnered product candidates through collaboration with third parties, including our early-stage CNS assets and oncology product candidates.

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

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

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. In addition, there have been a significant number of recent business combinations among large biopharmaceutical companies that have resulted in a reduced number of potential future collaborators. If a future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

***We have a memorandum of understanding with EmpathBio to evaluate a combination of EMP-01, an MDMA derivative as an adjunct to behavioral therapy, and BNC210 for the treatment of PTSD which could be impacted by the risks associated with the development of psychedelic scheduled drugs.***

In the United States, MDMA is listed by the U.S. Drug Enforcement Administration ("DEA") as a Schedule I substance under the Controlled Substance Act ("CSA"). The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, have no currently accepted medical use in the United States, lack accepted safety for use under medical supervision, and may not

be prescribed, marketed or sold in the United States. Pharmaceutical products approved for use in the United States may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II substances are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II substances is further restricted. For example, they may not be refilled without a new prescription and may have a black box warning. Most, if not all, state laws in the United States classify MDMA as Schedule I controlled substance. For any product containing MDMA to be available for commercial marketing in the United States, MDMA must be rescheduled, or the product itself must be scheduled, by the DEA to Schedule II, III, IV or V. Commercial marketing in the United States will also require scheduling-related legislative or administrative action, which can further delay the path to market. Any clinical development of EMP-01 or the use of BNC210 in combination with EMP-01 will require FDA approval, and MDMA's controlled substance status may negatively impact the FDA's decision regarding whether to approve the clinical development.

Scheduling determinations by the DEA are dependent on FDA approval of a substance or a specific formulation of a substance. Therefore, while MDMA is a Schedule I controlled substance, products approved by the FDA for medical use in the United States that contain MDMA should be placed in Schedules II-V, since approval by the FDA satisfies the "accepted medical use" requirement. If EMP-01 receives FDA approval, we anticipate that the DEA will make a scheduling determination and place it in a schedule other than Schedule I in order for it to be prescribed to patients in the United States. This scheduling determination will be dependent on FDA approval and the FDA's recommendation as to the appropriate schedule. During the review process, and prior to approval, the FDA may determine that it requires additional data, either from non-clinical or clinical studies, including with respect to whether, or to what extent, the substance has abuse potential. This may delay the approval process and any potential rescheduling process. That delay would be dependent on the quantity of additional data required by the FDA. This scheduling determination will require the DEA to conduct notice and comment rule making including issuing an interim final rule. Such action will be subject to public comment and requests for hearing which could affect the scheduling of these substances. There can be no assurance that the DEA will make a favorable scheduling decision. Even assuming categorization as a Schedule II or lower controlled substance (i.e., Schedule III, IV or V), at the federal level, such substances would also require scheduling determinations under state laws and regulations. Any failure by the DEA to make a favorable scheduling decision with respect to EMP-01 would delay clinical trials and potentially prevent the commercialization of any combination of BNC210 with EMP-01.

Individual U.S. states have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule product candidates. While some states automatically schedule a drug based on federal action, other states schedule drugs through rule making or a legislative action. State scheduling may delay or prevent commercial sale of EMP-01 in certain states even if it obtains federal regulatory approval, which would in turn prevent the commercialization of any combination of BNC210 with EMP-01 in those states.

***Combination-use products, including a potential combination of EMP-01 and BNC210, may present safety or supply issues that could delay or prevent development and approval of our product candidates.***

We are exploring BNC210 in combination with EMP-01, and could potentially explore other combination therapies with future product candidates. We will not be able to market and sell BNC210 or any product candidate we develop in combination with any unapproved therapies that do not ultimately obtain marketing approval. There are risks similar to the ones described for our products currently in development and clinical trials that result from the fact that such therapies are unapproved, such as the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval.

Furthermore, we cannot be certain that we will be able to obtain a steady supply of such therapies for use in developing combinations with our product candidates on commercially reasonable terms or at all. Any failure to

obtain such therapies for use in clinical development, and the expense of purchasing therapies in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our product candidates as commercially viable therapies.

Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risk that the FDA or similar regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product candidate, or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Similarly, if the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA or similar regulatory authorities outside of the United States may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or withdraw their approval, or if safety, efficacy, manufacturing, or supply issues arise with the drugs we choose to evaluate in combination with BNC210 or any product candidate we develop, we may be unable to obtain approval of, or market BNC210 or any product candidate we develop.

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

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

We and any third parties that we contract with are required to comply with regulations and requirements, including GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area (“EEA”) and comparable foreign regulatory authorities for any drugs in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or the third parties we contract with fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure that, upon inspection, the FDA will determine that any of our current or future clinical trials will comply with GCP requirements. In addition, our clinical trials must be conducted with current or future product candidates produced under cGMP regulations and will require a large number of study subjects. Our failure or the failure of third parties that we may contract with to comply with these regulations or to recruit a sufficient number of subjects may require us to repeat some aspects of a specific, or an entire, clinical trial, which would delay the marketing approval process and could also subject us to

enforcement action. We also are required to register certain ongoing clinical trials and provide certain information, including information relating to the trial's protocol, on a government-sponsored database, such as ClinicalTrials.gov, within specific timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we have and will continue to design the preclinical studies and clinical trials for our current or future product candidates, or be involved in the design when other parties sponsor the studies or trials, we anticipate that third parties will conduct all of our preclinical studies and clinical trials. As a result, many important aspects of our preclinical and clinical development, including their conduct, timing and response to the ongoing COVID-19 pandemic, are and will be outside of our direct control. Our reliance on third parties to conduct future clinical trials also results in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff, and we cannot control whether or not they will devote sufficient time and resources to our product candidates. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

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

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

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

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

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

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

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

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

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

While we seek to maintain adequate inventory of the drug product and drug substance used in our current or future product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain drug product and drug substance from alternate sources at acceptable prices in a timely manner, could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

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

We have only six full-time employees, one part-time employee, two full-time consultants and three part-time consultants and, as a result, we rely on outsourcing arrangements for a significant portion of our activities,

including clinical research, data collection and analysis and manufacturing. We may have limited control over these third parties and we cannot guarantee that they will perform their obligations in an effective and timely manner.

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

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

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

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

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

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

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

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our current or future product candidates or may elect not to continue or renew development or commercialization of our current or future product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our current or future product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our current or future product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property; and
- collaborators may not pay milestones and royalties due to the company in a timely manner.

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

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

We do not have our own manufacturing facilities or personnel and currently rely, and expect to continue to rely, on third parties for the manufacture of our current or future product candidates. These third-party

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

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

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

***The COVID-19 pandemic has and could continue to materially and adversely impact our business, including our clinical trials, supply chain and business development activities.***

In December 2019, a novel strain of coronavirus, SARS-CoV-2 which causes the disease COVID-19, was first reported in Wuhan, China and has since become a global pandemic. In an effort to contain the spread of COVID-19, many countries, including China, the United States and most other jurisdictions around the world, have imposed unprecedented restrictions on travel, business closures, quarantines and lock-downs, resulting in a substantial reduction in economic activity. On January 30, 2020, the World Health Organization ("WHO"), declared this COVID-19 outbreak a Public Health Emergency of International Concern. On February 28, 2020, the WHO increased the assessment of the risk of spread and the risk of impact of COVID-19 to "very high" at a global level. On March 11, 2020, the WHO declared the COVID-19 outbreak a pandemic.

As COVID-19 has evolved into a worldwide pandemic, it has resulted in adverse effects in the global economy and financial markets, such as significant declines in the global stock markets. We may experience limitations on employee resources in the future, including because of sickness of employees or their families. The effects of government actions and our own policies and those of third parties to reduce the spread of COVID-19 have and may continue to negatively impact productivity and slow down or delay our ongoing and future clinical trials, preclinical studies and research and development activities, and have caused, and may further cause, disruptions to our supply chain and may impair our ability to execute our business development strategy. For example, we may in the future experience enrollment delays and patient retention issues in our clinical trials as a result of the impact of COVID-19. In the event that government authorities were to enhance current restrictions, our employees and those of our third party contractors who currently are not telecommuting may no longer be able to access our or their facilities, as applicable, and our operations may be limited or curtailed.

The COVID-19 pandemic is ongoing, in large part due to the prevalence of new variants of the SARS-CoV-2 virus, and, accordingly, we may continue to experience ongoing disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- difficulties in enrolling and retaining patients in our Phase 2 SAD and PTSD clinical trial of BNC210 or our other clinical trials in the future;
- delays in receiving authorizations from local regulatory authorities, or approvals from IRBs or ethics committees to conduct our planned clinical trials;
- risk that patients may withdraw from our clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine, which could adversely influence the results of a clinical trial by increasing the number of adverse events or patients lost to follow-up;
- delays or difficulties in clinical site initiation or expansion, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruptions in global shipping that may affect the transport of clinical trial materials;
- changes in regulations as part of a response to the COVID-19 outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue such clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- delays in necessary interactions with regulators, ethics committees and other agencies and contractors due to limitations in employee resources or forced furloughs of government or contractor personnel;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may adversely affect review and approval timelines; and
- refusal of a regulatory authority to accept data from clinical trials in affected geographies outside its jurisdiction.

These and other disruptions in our operations and the global economy could negatively impact our business, operating results and financial condition.

Our clinical trials have been, and may in the future be, affected by the COVID-19 pandemic. We may experience enrollment delays and patient retention issues in our clinical trials as a result of the impact of COVID-19. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may be adversely impacted. We and our CROs have also made certain adjustments to the operation of our trials in an effort to ensure the monitoring and safety of patients and minimize risks to trial integrity during the pandemic in accordance with the guidance issued by the FDA on March 18, 2020 and most recently updated on January 27, 2021, and may need to make further adjustments in the future. Many of these adjustments are new and untested, may not be effective in mitigating risks, and may have unforeseen effects on the enrollment, progress and completion of these trials and the findings from these trials. These events could delay our clinical trials, increase the cost of completing our clinical trials and negatively impact the integrity, reliability or robustness of the data from our clinical trials.

In addition, quarantines, shelter-in-place and similar government orders related to COVID-19 or other infectious diseases, or the perception that such orders, shutdowns or other restrictions on the conduct of business

operations could occur, could adversely affect personnel at third-party manufacturing facilities upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for our product candidates. To the extent our suppliers and service providers are unable to comply with their obligations under our agreements with them or they are otherwise unable to deliver or are delayed in delivering goods and services to us due to the COVID-19 pandemic, our ability to continue meeting clinical supply demand for our product candidates or otherwise advancing development of our product candidates may become impaired.

The spread of COVID-19 and actions taken to reduce its spread may also materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, it has already caused, and could result in further, significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position. In addition, the trading prices for other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our ADSs or other securities and such sales may be on unfavorable terms.

COVID-19 and actions taken to reduce its spread continue to rapidly evolve. For example, one vaccine for COVID-19 was granted Emergency Use Authorization by the FDA in late 2020 and subsequently granted approval by the FDA and two others were granted Emergency Use Authorization by the FDA in late 2020 and early 2021, and more may be approved or authorized in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials. The extent to which COVID-19 may further impede the development of our product candidates, reduce the productivity of our employees, disrupt our supply chains, delay our clinical trials, reduce our access to capital or limit our business development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in China, Australia, the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this “Risk Factors” section, such as those relating to the timing and results of our clinical trials and our financing needs.

***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.

**Risks Related to Commercialization of Our Product Candidates**

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

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

not become profitable. Market acceptance of our current or future product candidates, if approved, will depend on a number of factors, including, among others:

- the efficacy of our current or future product candidates as demonstrated in clinical trials, and, if required by any applicable regulatory authority in connection with the approval for the applicable indications, to provide patients with incremental health benefits, as compared with other available medicines;
- the timing of market introduction of the product candidates and potential advantages to alternative treatments;
- limitations or warnings contained in the labeling approved for our current or future product candidates by the FDA or other applicable regulatory authorities;
- the clinical indications for which our current or future product candidates are approved;
- publicity concerning our products or competing products and treatments;
- Our ability to obrain and maintain intellectual property protection;
- pricing and cost effectiveness;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness of our current or future product candidates;
- our ability to obtain sufficient third-party coverage or reimbursement; or
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

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

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

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

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

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, once approved;

- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

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

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

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

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

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

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

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

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

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

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

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

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

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

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that

reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price ("ASP") and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical drugs are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical drugs, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our drugs may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

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

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

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

We currently carry clinical trial liability insurance in the amount of A$20.0 million in the aggregate, but there can be no assurance that we will be able to maintain such insurance or that the amount of such insurance will be adequate to cover claims. We could be materially and adversely affected if we were required to pay damages or incur defense costs in connection with a claim outside the scope of indemnity or insurance coverage, if the indemnity is not performed or enforced in accordance with its terms or if our liability exceeds the amount of applicable insurance. In addition, there can be no assurance that insurance will continue to be available on terms acceptable to us, if at all, or that if obtained, the insurance coverage will be sufficient to cover any potential claims or liabilities. Similar risks would exist upon the commercialization or marketing of any drugs by us or our collaborators.

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

- decreased demand for any of our future drugs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- costs of litigation;
- distraction of management; and
- substantial monetary awards to plaintiffs.

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

**Risks Related to Regulation of Our Industry**

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

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

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

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

The time required to obtain approval by the FDA, EMA and comparable authorities is unpredictable, typically takes many years following the commencement of clinical trials, and depends upon numerous factors. The FDA, EMA and comparable authorities have substantial discretion in the approval process and we may encounter matters with the FDA, EMA or such comparable authorities that requires us to expend additional time and resources and delay or prevent the approval of our product candidates. For example, the FDA or EMA may

require us to conduct additional studies or trials for product candidates either prior to or post-approval, such as additional drug-drug interaction studies or safety or efficacy studies or trials, or it may object to elements of our clinical development program such as the number of subjects in our current clinical trials from the United States. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or result in a decision not to approve an application for regulatory approval. Despite the time and expense exerted, failure can occur at any stage. Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

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

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

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

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

We have not completed all the clinical trials necessary to support an application with the FDA, EMA or other regulatory authority for approval to market any of our product candidates. Before obtaining regulatory approvals for the commercial sale of our drugs, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that the product candidate is both safe and effective for use in each target indication. Clinical trials often fail to demonstrate safety and efficacy of the product candidate studied for the

target indication. Most product candidates that commence clinical trials are never approved as drugs. If our product candidates are not shown to be both safe and effective in clinical trials, we will not be able to obtain regulatory approval or commercialize these product candidates. In such case, we would need to develop other compounds and conducting associated preclinical studies and clinical trials, as well as the potential need for additional financing, would have a material adverse effect on our business, financial condition, results of operations and prospects.

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

***Changes in methods of product candidate manufacturing or formulation 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 pharmacometric analysis as necessary to give us a higher probability of success in a subsequent PTSD trial. This has 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. There can be no assurance we will not have to alter manufacturing methods or formulations in the future which may result in additional costs or delays and materially adverse our business.

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

Sales of our approved drugs will be subject to U.S. and non-U.S. regulatory requirements governing clinical trials and regulatory approval, and we plan to seek regulatory approval to commercialize our product candidates in the United States, the EEA, and other countries. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. For example, approval in the United States by the FDA does not ensure approval by the regulatory authorities in other countries or jurisdictions, and similarly approval by a non-U.S. regulatory authority, such as the EMA, does not ensure approval by regulatory authorities in other countries, including by the FDA. However, the failure to obtain approval in one jurisdiction may have a negative impact on our ability to obtain approval elsewhere. Approval processes and regulatory requirements vary among

countries and can involve additional drug testing and validation and additional administrative review periods. Even if a drug is approved, the FDA or EMA, as the case may be, may limit the indications for which the drug may be marketed, require extensive warnings on the drug labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for a drug is also subject to approval. Regulatory authorities in other countries also have their own requirements for approval of product candidates with which we must comply prior to marketing in those countries. Obtaining non-U.S. regulatory approvals and compliance with such non-U.S. regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our current and any future drugs, in certain countries. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our product candidates will be unrealized.

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

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

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The U.S. Department of Health and Human Services (“HHS”), Office of Inspector General (“OIG”), heavily scrutinizes relationships between pharmaceutical companies and persons in a position to generate referrals for or the purchase of their products, such as physicians, other healthcare providers, and pharmacy benefit managers, among others;
- the federal civil monetary penalty laws and civil and criminal false claims laws and, such as the federal False Claims Act, which imposes criminal and civil penalties, including through civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. Federal Government, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. Federal Government. In addition, the Government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false of fraudulent claim for purposes of the False Claims Act. Manufacturers can be held liable under the False Claims Act, even when they do not submit claims directly to government payors, if they are deemed to have “caused” the submission of the claim. The False Claims Act allows private individuals acting as “whistleblowers” to bring actions on the U.S. Federal Government’s behalf and to share in any recovery;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback

Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services information related to certain payments and other transfers of value to physicians (as defined by statute), certain non-physician practitioners (including nurse practitioners, certified nurse anesthetists, physician assistants, clinical nurse specialists, anesthesiology assistants and certified nurse midwives) as well as teaching hospitals. Manufacturers are also required to disclose ownership and investment interests held by physicians and their immediate family members;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers.

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

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

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

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

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners may engage in fraudulent conduct or other illegal activities. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate: (i) the regulations of the FDA, EMA and other regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad; or (iv) laws that require the reporting of true, complete and accurate financial information and data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements.

Activities subject to these laws could also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent misconduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations.

Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

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

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of the Center for Medicare and Medicaid Innovation at the Centers for Medicare & Medicaid Services ("CMS") to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

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

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

- On 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 May 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, beginning January 1, 2024.
- 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.

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 manner in which manufacturers set prices for their marketed products, which has already resulted in several U.S.

Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs.

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

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

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

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

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

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

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In Australia, Australia's Privacy Act 1988 (Cth), as amended (the "Privacy Act"), 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 Office of the Australian Information Commissioner ("OAIC") must be notified as soon as a business determines there are reasonable grounds to believe a notifiable data breach has occurred, and within 30 days. A failure to notify can result in significant penalties. The Privacy Act, and applicable penalties, are the subject of an ongoing review by the Australian Attorney-General's Department. Proposed amendments to the Privacy Act enforcement regime are likely to result in a significant increase in penalties for interferences with privacy and/or the failure to notify the OAIC under the mandatory data breach notification scheme. In addition to the Privacy Act, certain Australian federal, state and territory legislation provides for additional regulatory oversight and enforcement in respect of the handling of health information and records as well as data breach notification requirements in some circumstances. These instruments may provide for regulatory investigations, fines, injunctive relief or enforceable undertakings in the event of the unauthorized access to, use, or handling of health information or records. Further, the sending of commercial electronic messages without prior consent is prohibited under Australia's Spam Act 2003 (Cth). Violations of this legislation are subject to significant penalties, particularly 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, industry standards, and corrective regulatory enforcement actions 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, among other things, 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. For example, 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. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Similar laws have passed in Virginia, Colorado, Connecticut and Utah, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. 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. In July 2020, the Court of Justice of the EU ("CJEU") limited how organizations could lawfully transfer personal data from the EU/EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses ("SCCs"). In March 2022, the United States and EU announced a new regulatory regime intended to replace the invalidated regulations; however, this new EU-US Data Privacy Framework has not been implemented beyond an executive order signed by President Biden on October 7, 2022 on Enhancing Safeguards for United States Signals Intelligence Activities. With respect to the restrictions on use of SCCs, the European Commission issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021; existing SCC arrangements must be migrated to the revised clauses by December 27, 2022. The new SCCs apply only to the transfer of personal data outside of the EEA and not the United Kingdom. The United Kingdom's Information Commissioner's Office has published new data transfer standard contracts for transfers from the United Kingdom under the United Kingdom GDPR ("UK GDPR"). This new documentation will be mandatory for relevant data transfers from September 21, 2022; existing standard contractual clauses arrangements must be migrated to the new documentation by March 21, 2024. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Further, following the withdrawal of the United Kingdom from the EU on January 31, 2020, and the expiration of the transition period, from January 1, 2021, from January 1, 2021, companies have had to comply with the GDPR and also 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. The European Commission adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the United Kingdom adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews or extends that decision. In September 2021, the United Kingdom government launched a consultation on its proposals for wide-ranging reform of United Kingdom data protection laws following Brexit and the response to this consultation was published in June 2022. There is a risk that any material changes which are made to the United Kingdom data protection regime could result in the European Commission reviewing the United Kingdom adequacy decision, and the United Kingdom losing its adequacy decision if the European Commission deems the United Kingdom to no longer provide adequate protection for personal data.

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

**Risks Related to Our Intellectual Property**

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

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

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

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

The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. For example, our pending patent applications may be subject to third-party pre-issuance submissions of prior art to the USPTO or our issued patents may be subject to post-grant review proceedings, oppositions, derivations, reexaminations, or inter partes review proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which

could limit our ability to stop others from using or commercializing similar or identical technologies and products, or limit the duration of the patent protection of our technologies and products. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. If the breadth or strength of the claims of our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize our current product candidates or future product candidates, or could have a material adverse effect on our ability to raise funds necessary to continue our research programs or clinical trials.

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

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

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

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

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

The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse, including due to the effect of the COVID-19 pandemic on us or our patent maintenance vendors, can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

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

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

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

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

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

After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

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

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

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

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

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

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

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

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

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

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

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

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

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

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

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

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

Moreover, we may become party to future adversarial proceedings regarding our patent portfolio or the patents of third parties. Such proceedings could include supplemental examination or contested post-grant proceedings such as review, reexamination, inter parties review, interference or derivation proceedings before the USPTO and challenges in U.S. District Court. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims

that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Also, our patents may be subjected to opposition, post-grant review or comparable proceedings lodged in various foreign, both national and regional, patent offices.

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

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

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

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

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

Further, competitors or third parties may infringe or otherwise violate our intellectual property. To counter infringement or other violations, we may be required to file claims, which can be expensive and time consuming.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We also rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our discovery and

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

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

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

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

As is common in the biotechnology and pharmaceutical industries, we employ individuals and engage the services of consultants who previously worked for other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that our consultants have used or disclosed trade secrets or other proprietary information of their former or current clients. Litigation may be necessary to defend against

these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities.

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

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

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

**Risks Related to this Offering and Our ADSs**

***The trading price of our ordinary shares has been volatile, and that of our ADSs may be volatile, and you may not be able to resell the ADSs at or above the price you paid.***

The trading price of our ordinary shares have been and may continue to be volatile on the ASX market and the trading price of our ADSs following this offering could be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in this "Risk Factors" section of this prospectus and positive, negative or unexpected developments relating to:

- results from, or any delays in, clinical trial programs relating to our product candidates, including the ongoing and future clinical trials for BNC210, and Merck and Carina Biotech collaboration 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;
- announcements relating to future collaborations or our existing collaborations, including decisions regarding the exercise by our collaboration partners of their options, if any, or any termination by them of their collaborations with us;
- 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 the ADSs;
- trading prices and trading volume of our ordinary shares on the ASX;
- sales of our ordinary shares or ADSs by us, our senior management and directors or our shareholders in the future;
- general economic and market conditions and overall fluctuations in the United States and international 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 ordinary shares or ADSs. 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.

***Fluctuations in currency exchange rates mat have a material adverse effect on our results of operations and the value of any investment in our ADSs.***

Although our financial results are reported in Australian Dollars, historically a portion of our operating expenses and a substantial portion of our revenue have been denominated in currencies other than the Australian Dollar. As a result, changes in the exchange rate between the Australian Dollar and other currencies, particularly the U.S. Dollar, could have a material adverse effect on our business, results of operations and financial condition that could adversely affect the trading price of our ADSs. Accordingly, volatility in foreign currency exchange rates may have a material adverse impact on our financial condition, results of operations and liquidity and distort period-to-period comparisons of our financial condition and operating results. We have not historically used foreign exchange contracts to help manage foreign exchange rate exposures.

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

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, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the conflict in Ukraine, 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, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business, financial condition and results of operations and the price of our ADSs.

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

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our ADSs. Such a de-listing would likely have a negative effect on the price of our ADSs and would impair the ability of investors to sell or purchase our ADSs when any investor may wish to do so. In the event of a de-listing, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our ADSs to become listed again, stabilize the market price or improve the liquidity of our ADSs, prevent our ADSs from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

***Sales of a substantial number of our ordinary shares or ADSs by our existing shareholders in the public market, or the perception that such sales may occur, could depress the trading price of our ordinary shares and ADSs.***

Sales of a substantial number of our ADSs or ordinary shares in the public market or the perception that these sales may occur could significantly reduce the market price of our ADSs and impair our ability to raise adequate capital. As of June 30, 2022, we had a total of 1,881,408 ADSs outstanding and 1,353,350,744 ordinary shares outstanding (including 338,653,440 ordinary shares underlying our ADSs), assuming no exercise of outstanding options, which are freely tradable, without restriction, in the public market, unless they are held or purchased by one of our affiliates. ADSs held by our affiliates are eligible for sale in the public market and will be subject to volume limitations under Rule 144 under the Securities Act.

***Future sales of our ordinary shares or ADSs, or the perception that such sales may occur, could depress the trading price of our ordinary shares and ADSs.***

After the completion of this offering, we expect to have ADSs outstanding and ordinary shares outstanding, including the shares underlying the ADSs we are selling in this offering, which may be resold in the public market immediately after this offering. We and all of our directors and executive officers and our two largest shareholders have signed lock-up agreements for a period of days following the date of this prospectus, subject to specified exceptions, including exceptions allowing the transfer of ordinary shares purchased in the offering and open market purchases following the offering. See "Underwriting." The underwriters may, in their sole discretion and without notice, release all or any portion of the ordinary shares or ADSs subject to lock-up agreements. As restrictions on resale end, the market price of our ADSs and ordinary shares could drop significantly if the holders of these ADSs or ordinary shares sell them or are perceived by the market as intending to sell them. These factors could also make it more difficult for us to raise additional funds through future offerings of our ordinary shares, ADSs or other securities.

***Investors purchasing the ADSs will incur immediate and substantial dilution in the book value of their shares.***

We expect the public offering price of our ADSs in this offering to be substantially higher than the net tangible book value per ADS prior to this offering. Therefore, if you purchase ADSs in this offering, you will pay a price per ADS that substantially exceeds our net tangible book value per ADS after this offering. To the extent outstanding options or warrants are exercised for ordinary shares, you may experience further dilution. Based on the assumed public offering price of $ per ADS, which was the last reported sale price of our ADSs on the Nasdaq Global Market on , 2022, you will experience immediate dilution of $ per ADS, representing the difference between our net tangible book value per ADS and per ordinary share after giving effect to this and the assumed offering price. This dilution is due to our investors who purchased shares prior to this offering having paid substantially less when they purchased their ordinary shares than the price of the ADSs offered to the public in this offering. We may also issue additional ordinary shares, ADSs, performance rights, options, warrants and other securities in the future that may result in further dilution of your ADSs. As a result of the dilution to investors purchasing ADSs in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. See "Dilution" for a calculation of the extent to which your investment will be diluted.

***We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.***

We will have broad discretion in the application of the net proceeds that we receive from this offering as well as of our existing cash and cash equivalents and non-current financial assets, and we may spend or invest these funds in a way with which our shareholders or holders of the ADSs disagree. Our failure to apply these funds effectively could harm our business and financial condition. Pending their use, we may invest the net proceeds from the offering in a manner that does not produce income or that loses value. These investments may not yield a favorable return to our investors.

***Our executive officers, directors, principal shareholders and their affiliates will continue to exercise significant influence over our company after this offering, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control.***

Immediately following the completion of this offering, the existing holdings of our executive officers, directors, principal shareholders and their affiliates will represent, based on their ownership of our outstanding ordinary shares as of June 30, 2022 and beneficial ownership, in the aggregate, of approximately % of our outstanding ordinary shares, assuming no exercise of the underwriters' option to acquire additional ADSs in this offering, assuming we issue the number of ADSs as set forth on the cover page of this prospectus and without giving effect to any potential purchases by such persons in this offering. Assuming full exercise of all outstanding vested and exercisable options and warrants held by our executive officers, directors, principal

shareholders and their affiliates as of June 30, 2022, their beneficial ownership increases to approximately % of our outstanding equity interests. Furthermore, many of our current directors were appointed by our principal shareholders. As a result, such persons or their appointees to our board of directors, acting together, have and will continue to have the ability to control or significantly influence all matters submitted to our board of directors or shareholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other shareholders. These shareholders acquired their ordinary shares for substantially less than the price of the ADSs being acquired in this offering, and these shareholders may have interests with respect to their ordinary shares that are different from those of investors in this offering. The concentration of voting power among these shareholders may have an adverse effect on the price of our ADSs. In addition, this concentration of ownership might adversely affect the market price of our ADSs by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

See the section of this prospectus titled “Principal Shareholders” for more information regarding the ownership of our outstanding ordinary shares by our executive officers, directors, principal shareholders and their affiliates.

***An active, liquid trading market for our ADSs may not be maintained.***

***We can provide no assurance that we will be able to maintain an active trading market for our ADSs. The lack of an active market may impair the ability of any investor to sell our ADSs 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 shares 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.***

Certain of our existing shareholders, including those affiliated with members of our board of directors, may purchase purchase ADSs in this offering at the offering price per ADS and on the same terms as the other purchasers in this offering. To the extent these existing shareholders purchase any ADSs in this offering, such purchase could reduce the available public float for our ADSs because such shareholders may be restricted from selling the securities by restrictions under applicable securities laws. As a result, any purchase of ADSs by such shareholders in this offering may reduce the liquidity of our ADSs relative to what it would have been had these ADSs been purchased by investors that were not existing shareholders.

***The dual listing of our ordinary shares and the ADSs may adversely affect the liquidity and value of the ADSs.***

In addition to our ADSs being listed on Nasdaq, our ordinary shares are listed on the ASX. We cannot predict the effect of this dual listing on the value of our ordinary shares and ADSs. However, the dual listing of our ordinary shares and ADSs may dilute the liquidity of these securities in one or both markets and may impair the development of an active trading market for the ADSs in the United States. The trading price of the ADSs could also be adversely affected by trading in our ordinary shares on the ASX.

***Our securities will be traded on more than one market and this may result in price variations.***

Our ordinary shares have been traded on the ASX since 1999, and our ADSs are traded on Nasdaq. Trading in our securities on these markets will take place in different currencies (U.S. dollars on Nasdaq and Australian

dollars on the ASX), and at different times (resulting from different time zones, trading days and public holidays in the United States and Australia). The trading prices of our securities on these two markets may differ due to these and other factors, including the fact that ASX and Nasdaq have different criteria for trading halts as well as different listing rules and disclosure requirements. Any decrease in the price of our ordinary shares on the ASX could cause a decrease in the trading price of our ADSs on Nasdaq.

***ADS holders may be subject to additional risks related to holding ADSs rather than ordinary shares.***

ADS holders do not hold ordinary shares directly and, as such, are subject to, among others, the following additional risks:

- as an ADS holder, we will not treat you as one of our shareholders and you will not be able to exercise shareholder rights, except through the American Depositary Receipt ("ADR"), depositary as permitted by the deposit agreement;
- distributions on the ordinary shares represented by your ADSs will be paid to the ADR depositary, and before the ADR depositary makes a distribution to you on behalf of your ADSs, any withholding taxes that must be paid will be deducted. Additionally, if the exchange rate fluctuates during a time when the ADR depositary cannot convert the foreign currency, you may lose some or all of the value of the distribution; and
- we and the ADR depositary may amend or terminate the deposit agreement without the ADS holders' consent in a manner that could prejudice ADS holders.

***Your right as a holder of ADSs to participate in any future preferential subscription rights offering or to elect to receive dividends in ordinary shares may be limited, which may cause dilution to your holdings.***

The deposit agreement provides that the depositary will not make rights available to you unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act or exempted from registration under the Securities Act. If we offer holders of our ordinary shares the option to receive dividends in either cash or shares, under the deposit agreement the depositary may require satisfactory assurances from us that extending the offer to holders of ADSs does not require registration of any securities under the Securities Act before making the option available to holders of ADSs. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, ADS holders may be unable to participate in our rights offerings or to elect to receive dividends in shares and may experience dilution in their holdings. In addition, if the depositary is unable to sell rights that are not exercised or not distributed or if the sale is not lawful or reasonably practicable, it will allow the rights to lapse, in which case you will receive no value for these rights.

***You may be subject to limitations on the transfer of your ADSs and withdrawal of the underlying ordinary shares.***

Your ADSs are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of your ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason subject to your right to cancel your ADSs and withdraw the underlying ordinary shares. Temporary delays in the surrendering of your ADSs and withdrawal of the underlying ordinary shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting or we are paying a dividend on our ordinary shares. In addition, you may not be able to cancel your ADSs and withdraw the underlying ordinary shares when you

owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities.

***You must act through the ADR depositary to exercise your voting rights and, as a result, you may be unable to exercise your voting rights on a timely basis.***

As a holder of ADSs (and not the ordinary shares underlying your ADSs), we will not treat you as one of our shareholders, and you will not be able to exercise shareholder rights directly. The ADR depositary will be the holder of the ordinary shares underlying your ADSs, and ADS holders will be able to exercise voting rights with respect to the ordinary shares represented by the ADSs only in accordance with the deposit agreement relating to the ADSs. There are practical limitations on the ability of ADS holders to exercise their voting rights due to the additional procedural steps involved in communicating with these holders. For example, holders of our ordinary shares will receive notice of shareholders' meetings by mail and will be able to exercise their voting rights by either attending the shareholders meeting in person or voting by proxy. ADS holders, by comparison, will not receive notice directly from us. Instead, in accordance with the deposit agreement, we will provide notice to the ADR depositary of any such shareholders meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date. If we so instruct, the ADR depositary will mail to holders of ADSs the notice of the meeting and a statement as to the manner in which voting instructions may be given by holders as soon as practicable after receiving notice from us of any such meeting. To exercise their voting rights, ADS holders must then instruct the ADR depositary as to voting the ordinary shares represented by their ADSs. Due to these procedural steps involving the ADR depositary, the process for exercising voting rights may take longer for ADS holders than for holders of ordinary shares. The ordinary shares represented by ADSs for which the ADR depositary fails to receive timely voting instructions will not be voted.

***Bionomics Limited may be classified as a passive foreign investment company for U.S. federal income tax purposes, which could result in adverse U.S. federal income tax consequences to U.S. investors in the ADSs or ordinary shares.***

A non-U.S. corporation will be considered a "passive foreign investment company" ("PFIC") for any taxable year if (i) at least 75% of its gross income is passive income, or (ii) at least 50% of the value of its assets (generally based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income. For purposes of the above calculations, a non-U.S. corporation that owns, directly or indirectly, at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets of the other corporation and received directly its proportionate share of the income of the other corporation. Passive income generally includes dividends, interest, certain rents or royalties, foreign currency or other investment gains and certain other categories of income.

Based on the value of Bionomics Limited's assets for its taxable year ending June 30, 2022, including the value of its goodwill, and the composition of its income and assets in such taxable year, we do not believe Bionomics Limited was a "passive foreign investment company" ("PFIC") for its taxable year ending June 30, 2022. However, the application of the PFIC rules is subject to uncertainty in several respects. Furthermore, a separate determination must be made after the close of each taxable year as to whether Bionomics Limited is a PFIC for that year, based on its income for the entire year and the value of its assets throughout the year. Accordingly, we cannot assure you that Bionomics Limited was not a PFIC for its taxable year ending June 30, 2022 or that it will not be a PFIC for its current taxable year or any future taxable year. In particular, Bionomics Limited's PFIC status may depend, in part, on the receipt and treatment of other sources of income (including government grants) and having active income from other sources in excess of passive income from investments. For purposes of the asset test described above, goodwill is generally characterized as an active asset to the extent it is associated with business activities that produce active income, and the value of Bionomics Limited's assets, including goodwill, generally is determined by reference to the market price of our ADSs or ordinary shares, which may fluctuate considerably, especially in times of high market volatility. Cash is generally characterized

as a passive asset for these purposes, so the composition of Bionomics Limited's income and assets will be affected by how, and how quickly, it spends the cash it holds or the cash raised in any offering, including this offering. If Bionomics Limited were to be treated as a PFIC for any taxable year during which a U.S. Holder (as defined below under "Taxation—U.S. Federal Income Tax Considerations") holds an ADS or ordinary share, certain adverse U.S. federal income tax consequences could apply to such U.S. Holder. See "Taxation—U.S. Federal Income Tax Considerations—Passive Foreign Investment Company Considerations."

***If a United States person is treated as owning at least 10% of Bionomic Limited's ordinary shares, such holder may be subject to adverse U.S. federal income tax consequences.***

If a United States person is treated as owning, directly, indirectly or constructively, at least 10% of the value or voting power of Bionomic Limited's ordinary shares or ADSs, such person may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group, if any. If our group includes one or more U.S. subsidiaries (as is currently the case), certain of our non-U.S. subsidiaries could be treated as controlled foreign corporations (even if Bionomics Limited is not treated as a controlled foreign corporation). A United States shareholder of a controlled foreign corporation may be required to annually report and include in its U.S. taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income" and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. Failure to comply with controlled foreign corporation reporting obligations may subject a United States shareholder to significant monetary penalties and may prevent the statute of limitations with respect to such United States shareholder's U.S. federal income tax return for the year for which reporting was due from starting. We cannot provide any assurances that we will assist investors in determining whether any of our non-U.S. subsidiaries is treated as a controlled foreign corporation or whether such investor is treated as a United States shareholder with respect to any of such controlled foreign corporations or that we will furnish to any investors information that may be necessary to comply with the reporting and tax paying obligations applicable under the controlled foreign corporation rules of the Internal Revenue Code of 1986, as amended (the "Code"). U.S. investors should consult their tax advisors regarding the potential application of these rules to their investment in our ordinary shares or ADSs.

***You may not receive dividends on our ordinary shares represented by the ADSs or any value for such dividend if it is illegal or impractical to make them available to holders of ADSs.***

While we do not anticipate paying any dividends on our ordinary shares in the foreseeable future, if such a dividend is declared, the depositary for the ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses. You will receive these dividends in proportion to the number of our ordinary shares your ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a dividend available to holders of ADSs. We have no obligation to take any other action to permit the dividend of the ADSs, ordinary shares, rights or anything else to holders of the ADSs.

This means that you may not receive the dividends we make on our ordinary shares or any value from them if it is unlawful or impractical to make them available to you. These restrictions may have a material adverse effect on the value of your ADSs. In addition, exchange rate fluctuations may affect the amount of Australian dollars that we are able to distribute, and the amount in U.S. dollars that our shareholders receive upon the payment of cash dividends or other distributions we declare and pay in Australian dollars, if any. These factors could harm the value of the ADSs, and, in turn, the U.S. dollar proceeds that holders receive from the sale of the ADSs.

***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 ADSs 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, reduced disclosure obligations regarding executive compensation in our periodic reports and any proxy statements, exemptions from the requirements of holding a nonbinding 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 prospectus. We cannot predict if investors will find our ADSs less attractive because we rely on these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and the trading price of our ADSs 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 IPO, (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our ADSs 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.

***As a foreign private issuer, we are permitted to rely on exemptions from certain Nasdaq corporate governance standards applicable to domestic U.S. issuers. This may afford less protection to holders of our shares.***

We are exempted from certain corporate governance requirements of Nasdaq by virtue of being a foreign private issuer. As a foreign private issuer, we are permitted to follow the governance practices of our home country, Australia, in lieu of certain corporate governance requirements of Nasdaq. As result, the standards applicable to us are considerably different than the standards applied to domestic U.S. issuers. For instance, we are not required to:

- have a majority of the board be independent (although all of the members of the audit committee must be independent under the Exchange Act);
- have a compensation committee and a nominating committee to be comprised solely of "independent directors"; or
- hold an annual meeting of shareholders no later than one year after the end of our fiscal year.

Although we do not currently intend to rely these "home country" exemptions, we may rely on some of these exemptions in the future. As a result, our shareholders may not be provided with the benefits of certain corporate governance requirements of Nasdaq.

***As a "foreign private issuer" in the United States, we are exempt from certain rules under U.S. securities laws and are permitted to file less information with the SEC than U.S. companies.***

As a "foreign private issuer," we are exempt from certain rules under the Exchange Act, that impose certain disclosure obligations and procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and the rules under the Exchange Act that deal with purchases and sales of the ADSs or our ordinary shares. Moreover, we are not required to file periodic reports

and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. In addition, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information. As a result of this classification, there may be less publicly available information concerning us than there is for U.S. public companies.

***We may lose our foreign private issuer status in the future, which could result in significant additional costs and expenses.***

As discussed above, we are a foreign private issuer, and therefore, we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act. The determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter. We would lose our foreign private issuer status if, for example, more than 50% of our ordinary shares are directly or indirectly held by residents of the United States and we fail to meet additional requirements necessary to maintain our foreign private issuer status. If we lose our foreign private issuer status on this date, we will be required to file with the SEC periodic reports and registration statements on U.S. domestic issuer forms, which are more detailed and extensive than the forms available to a foreign private issuer. We will also have to mandatorily comply with U.S. federal proxy requirements, and our officers, directors and principal shareholders will become subject to the short-swing profit disclosure and recovery provisions of Section 16 of the Exchange Act. In addition, we will lose our ability to rely upon exemptions from certain corporate governance requirements under the Nasdaq listing rules. As a U.S. listed public company that is not a foreign private issuer, we will incur significant additional legal, accounting and other expenses that we will not incur as a foreign private issuer, and accounting, reporting and other expenses in order to maintain a listing on a U.S. securities exchange.

***We currently report our financial results under IFRS, which differs in certain significant respect from U.S. generally accepted accounting principles ("U.S. GAAP").***

Currently we report our financial statements under IFRS. There have been and there may in the future be certain significant differences between IFRS and U.S. GAAP, including differences related to revenue recognition, intangible assets, share-based compensation expense, income tax and earnings per share. As a result, our financial information and reported earnings for historical or future periods could be significantly different if they were prepared in accordance with U.S. GAAP. In addition, we do not intend to provide a reconciliation between IFRS and U.S. GAAP unless it is required under applicable law. As a result, you may not be able to meaningfully compare our financial statements under IFRS with those companies that prepare financial statements under U.S. GAAP.

***Australian takeover laws may discourage takeover offers being made for us or may discourage the acquisition of a significant position in our ordinary shares or ADSs.***

We are incorporated in Australia and are subject to the takeover laws of Australia. Among other things, we are subject to the *Corporations Act 2001* (Cth) (the "Corporations Act"). Subject to a range of exceptions, the Corporations Act prohibits the acquisition of a direct or indirect interest in our issued voting shares if the acquisition of that interest will lead to a person's voting power in us increasing to more than 20%, or increasing from a starting point that is above 20% and below 90%. Australian takeover laws may discourage takeover offers being made for us or may discourage the acquisition of a significant position in our outstanding ordinary shares. This may have the ancillary effect of entrenching our board of directors and depriving or limiting our shareholders' or ADS holders' opportunity to sell their ordinary shares or ADSs and may further restrict the ability of our shareholders and ADS holders to obtain a premium from such transactions. See "Description of Share Capital—Change of Control".

***Our Constitution and Australian laws and regulations applicable to us may adversely affect our ability to take actions that could be beneficial to our shareholders and holders of our ADSs.***

As an Australian company, we are subject to different corporate requirements than a corporation organized under the laws of the states of the United States. Our Constitution, as well as the Corporations Act and the ASX Listing Rules, set forth various rights and obligations that are applicable to us as an Australian company listed on the ASX. These requirements may operate differently than those of many U.S. companies. You should carefully review the summary of these matters set forth under the section entitled "Description of Share Capital," as well as our Constitution, which is included as an exhibit to the registration statement to which this prospectus forms a part, prior to investing in the ADSs.

***You will have limited ability to bring an action against us or against our directors and officers, or to enforce a judgment against us or them, because we are incorporated in Australia, we conduct a majority of our operations in Australia, and the majority of our directors and officers reside outside the United States.***

We are incorporated under the laws of Australia and conduct substantially all of our operations in Australia. The majority of our directors and officers and certain other persons named in this prospectus are citizens and residents of countries other than the United States and all or a significant portion of the assets of the directors and officers and certain other persons named in this prospectus and substantially all of our assets are located outside of the United States. As a result, it may not be possible or practicable for you to effect service of process within the United States upon such persons or to enforce against them or against us judgments obtained in U.S. courts predicated upon the civil liability provisions of the federal securities laws of the United States. Even if you are successful in bringing such an action, there is doubt as to whether Australian courts would enforce certain civil liabilities under U.S. securities laws in original actions or judgments of U.S. courts based upon these civil liability provisions. In addition, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in Australia or elsewhere outside the United States. An award for monetary damages under U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered and is intended to punish the defendant. The enforceability of any judgment in Australia will depend on the particular facts of the case as well as the laws and treaties in effect at the time. The United States and Australia do not currently have a treaty or statute providing for recognition and enforcement of the judgments of the other country (other than arbitration awards) in civil and commercial matters. As a result, our holders of our ADSs may have more difficulty in protecting their interests through actions against us, our management or our directors than would shareholders of a corporation incorporated in a jurisdiction in the United States.

In addition, as a company incorporated in Australia, the provisions of the Corporations Act regulate the circumstances in which shareholder derivative actions may be commenced, which may be different to the circumstances for companies incorporated in the United States.

**General Risk Factors**

***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 U.S. publicly-traded company, and particularly is 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 ADSs will trade, have significant requirements on public companies, including many changes involving corporate governance. Management and other company personnel devote a substantial amount of time ensuring our compliance with these regulations. Accordingly, our legal, accounting and financial compliance expenses have significantly increased, and certain corporate actions will become more time-consuming and costly. For example, these regulations have made it more difficult to attract and retain qualified members of our board of directors and various corporate committees. Obtaining director and officer liability insurance is significantly more expensive as a public company.

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

The trading market for our ADSs 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 ADSs 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 ADSs or comment negatively about our prospects or the prospects of other companies operating in our industry, the trading price of our ADSs could decline significantly. There is no guarantee that equity research organizations affiliated with the underwriters of this offering 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 ADSs or our business, financial condition, results of operations and prospects.

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

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

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

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management will be required to report uponthe effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending June 30, 2023. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we will need to upgrade our information technology systems, implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff. If we or, if required, our auditor is unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our ADSs may decline.

Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. For as long

as we remain an emerging growth company, we intend to take advantage of the exemption permitting us not to comply with the independent registered public accounting firm attestation requirement. When we lose our status as an "emerging growth company" and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting.

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

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

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

## Special Note Regarding Forward-Looking Statements

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, prospective drugs, ongoing and planned clinical trials, regulatory approvals, research and development costs, timing and likelihood of success, as well as plans and objectives of management for future operations are forward-looking statements. These statements 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.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “would,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- 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 ongoing and future clinical trials and preclinical studies, and the reporting and interpretation of data from those trials and studies;
- our plans relating to commercializing our product candidates, if approved, 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 further 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;
- risks associated with the COVID-19 pandemic, which has and may continue to materially and adversely impact our business, preclinical studies and clinical trials;
- 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, and our ability to enter into, and negotiate favorable terms of, 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 needs for additional financing;
- 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 and the proceeds from this offering.
- 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;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; and
- our expectations regarding the period during which we will qualify as a foreign private issuer and be exempt from a number of rules under the U.S. securities laws and Nasdaq corporate governance rules and permitted to file less information with the SEC than U.S. companies.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described under the sections in this prospectus entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. The forward-looking statements contained in this prospectus are excluded from the safe harbor protection provided by the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act.

This prospectus also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

## Use of Proceeds

We estimate that the net proceeds to us from the sale of the ADSs that we are offering will be approximately $ million (or $ million if the underwriters exercise their option to purchase additional ADSs in full), assuming a public offering price of $ per ADS, which was the last reported sale price of our ADSs on the Nasdaq Global Market on , 2022, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase (decrease) in the assumed offering price of $ per ADS, which was the closing price of our ADSs on the Nasdaq Global Market on , 2022, the number of ordinary shares underlying each ADS, would increase (decrease) the net proceeds to us from this offering by approximately $ million, assuming that the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us. We may also increase or decrease the number of ADSs we are offering. Each increase (decrease) of 250,000 in the number of ADSs we are offering would increase (decrease) the net proceeds to us from this offering by approximately $ million, assuming that the assumed offering price remains the same, and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us. The information discussed above is illustrative only and will be adjusted based on the actual offering price and other terms of our offering determined at pricing.

We expect to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately $ for the continued development of BNC210 for the acute treatment of SAD, including the completion of the Phase 2 PREVAIL trial;
- approximately $ for the continued development of BNC210 for the treatment of PTSD, including completion of the ongoing Phase 2b ATTUNE clinical trial;
- approximately $ for the completion of chemistry, manufacturing and controls, long term safety and non-clinical pharmacology studies necessary to support Phase 3 pivotal trials of BNC210 for the treatment of SAD and PTSD; and
- the remainder for working capital, other research and development and general corporate purposes.

We believe, based on our current operating plan, that the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments in wealth management products, will be sufficient to fund our operations for at least the next 12 months. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development, the status of and results from preclinical studies or clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our product candidates, and any unforeseen cash needs. We may also use a portion of the net proceeds to in-license, acquire or invest in additional businesses, technologies, products or assets, although currently we have no specific agreements, commitments or understandings in this regard. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending our use of proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation instruments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

## Dividend Policy

We have not paid cash dividends on our ordinary shares 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 ordinary shares 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.

## Capitalization

The following table sets forth our cash and cash equivalents and our capitalization as of June 30, 2022, presented both in Australian and U.S. Dollars:

- on an actual basis; and
- on an as-adjusted basis to give further effect to the sale of ADSs in this offering at an assumed offering price of $ per ADS, which was the closing price of our ADSs on the Nasdaq Global Market on , 2022, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

| | As of June 30, 2022 | | | |
|---|---|---|---|---|
| | Actual(1) | Actual | As Adjusted(1) | As Adjusted |
| | $ | A$ | $ | A$ |
| | (in thousands) | | | |
| Cash and cash equivalents | $ 23,123 | $ 33,565 | $ | $ |
| Equity: | | | | |
| Capital | $ 149,971 | $ 217,696 | $ | $ |
| Share-based payments reserve | 4,366 | 6,337 | | |
| Foreign currency translation reserve | 4,262 | 6,186 | | |
| Accumulated losses | (119,391) | (173,307) | | |
| Total equity | 39,207 | 56,913 | | |
| Total capitalization | 39,207 | 56,913 | | |

(1) The amounts have been translated into U.S. Dollars from Australian Dollars based upon the exchange rate as published by the Reserve Bank of Australia as of June 30, 2022. These translations are merely for the convenience of the reader and should not be construed as representations that the Australian Dollar amounts actually represent such U.S. Dollar amounts or could be converted into U.S. Dollars at such rate.

Each $1.00 increase (decrease) in the assumed offering price of $ per ADS, which was the closing price of our ADSs on the Nasdaq Global Market on , 2022, would increase (decrease) the as-adjusted amount of each of cash and cash equivalents, total equity attributable to owners of the company and total capitalization by approximately $ , assuming that the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us. We may also increase or decrease the number of ADSs we are offering. Each increase (decrease) of 250,000 in the number of ADSs we are offering would increase (decrease) the as-adjusted amount of each of cash and cash equivalents, total equity attributable to owners of the company and total capitalization by approximately $ million, assuming that the assumed offering price remains the same, and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us. The as-adjusted information set forth above is illustrative only and our capitalization following the closing of this offering will be adjusted based on the actual offering price and other terms of our offering determined at pricing. You should read this information in conjunction with our financial statements and the related notes included in this prospectus and the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section and other financial information contained in this prospectus.

The number of ordinary shares in the table above is based on 1,353,350,744 ordinary shares outstanding as of June 30, 2022, and excludes:

- 79,056,617 ordinary shares issuable upon exercise of options outstanding as of June 30, 2022, at a weighted average exercise price of A$0.164 ($0.11) per share, of which options to purchase 31,065,275 ordinary shares were vested at a weighted average exercise price of A$0.14 ($0.04) per share; and

- 142,000,000 ordinary shares issuable upon exercise of warrants outstanding as of June 30, 2022 at a weighted average exercise price of A$0.06 ($0.04) per share, of which warrants to purchase 142,000,000 ordinary shares were vested at a weighted average exercise price of A$0.06 ($0.04) per share.

In addition, the number of ordinary shares in the table above excludes shares issuable pursuant to future awards granted to our employees under the Employee Equity Plan or that might be granted to our directors. Under the ASX Listing Rules, we cannot, without the approval of our shareholders, subject to specified exceptions, issue, during any 12 month period, any equity securities, or other securities with rights to convert into equity, if the number of those securities exceeds 15% of the number of shares on issue at the commencement of that 12 month period (or 25% if shareholder approval is obtained at our annual general meeting. See “Description of Share Capital--No Shareholder Approval of Offering”) (“Placement Capacity”). Under ASX Listing Rules, we can issue up to 100 million ordinary shares or 10% of the ordinary shares outstanding at the completion of the IPO to employees under the Employee Equity Plan without reducing our Placement Capacity due to a shareholder approval obtained at our 2021 Annual General Meeting. Awards to our employees above such threshold under the Employee Equity Plan would reduce our Placement Capacity in the year in which such awards are granted. Awards under the Employee Equity Plan may be issued as ADSs based on the applicable ratio of ordinary shares to ADSs.

## Dilution

If you invest in the ADSs in this offering, your ownership interest will be immediately diluted to the extent of the difference between the public offering price per ADS and the as-adjusted net tangible book value per ADS after this offering. Dilution results from the fact that the public offering price per ADS is substantially in excess of the net tangible book value per 180 ordinary shares underlying the ADSs.

As of June 30, 2022, we had a historical net tangible book value of A$38.7 million ($26.7 million), or A$0.03 ($0.02 ) per ordinary share, equivalent to A$5.12 ($3.55 ) per ADS (based on an assumed exchange rate of A$1.00 to $0.6889, which was the closing rate as of June 30, 2022 obtained from the website of the Reserve Bank of Australia). Net tangible book value per ADS represents total tangible assets less total liabilities, divided by the number of outstanding ordinary shares (including shares underlying the outstanding ADSs) multiplied by 180, the number of ordinary shares underlying each ADS.

After giving effect to the sale of ADSs that we are offering at an assumed public offering price of $ per ADS, which was the last reported sale price of our ADSs on the Nasdaq Global Market on , 2022, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our as-adjusted net tangible book value as of June 30, 2022 would have been A$ million ($ million), or A$ ($ ) per ADS. This amount represents an immediate increase in as-adjusted net tangible book value of $ per share and $ per ADS to our existing shareholders and an immediate dilution in as-adjusted net tangible book value of $ per ADS to new investors purchasing ADSs in this offering.

The following table illustrates this dilution (without giving effect to any exercise by the underwriters of their option to purchase additional ADSs):

| | | |
|---|---|---|
| Assumed public offering price per ADS | | $ |
| Historical net tangible book value per ADS as of June 30, 2022 | $0.02 | |
| Increase in as-adjusted net tangible book value per ADS attributable to this offering | | |
| As-adjusted net tangible book value per ADS after this offering | | |
| Dilution per ADS to new investors in this offering | | $ |

Each $1.00 increase (decrease) in the assumed public offering price of $ per ADS, which was the closing price of our ADSs on the Nasdaq Global Market on , 2022, would increase (decrease) the as-adjusted net tangible book value per ADS after this offering by $ , and dilution in as-adjusted net tangible book value per ADS to new investors by $ , assuming that the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us. We may also increase or decrease the number of ADSs we are offering. Each increase (decrease) of 250,000 in the number of ADSs we are offering would increase (decrease) our as-adjusted net tangible book value per ADS after this offering by $ per ADS and decrease (increase) the dilution to investors participating in this offering by $ per ADS, assuming that the assumed offering price remains the same, and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us. The as-adjusted information discussed above is illustrative only and will be adjusted based on the actual offering price and other terms of our offering determined at pricing.

If the underwriters exercise their option to purchase additional ADSs in full in this offering, the as-adjusted net tangible book value after the offering would be $ per ADS, the increase in as-adjusted net tangible book value per share to existing shareholders would be $ per ADS and the dilution per ADS to new investors would be $ per ADS, in each case assuming an offering price of $ per ADS, which was the closing price of our ADSs on the Nasdaq Global Market on , 2022.

The following table summarizes on the as-adjusted basis described above, as of June 30, 2022, the differences between the number of ADSs, or equivalent number of ordinary shares, purchased from us, the total consideration paid to us in cash and the average price per ADS, or the equivalent number of ordinary shares, paid by existing shareholders for ADSs, or the equivalent number of ordinary shares, issued prior to this offering and the price to be paid by new investors in this offering. The calculation below is based on the assumed public offering price of $ per ADS, which was the last reported sale price of our ADSs on the Nasdaq Global Market on , 2022, before deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

| | ADS or Equivalent Number of Shares Purchased(1) | | Total Consideration | | Average Price Per ADS or Equivalent Number of Shares |
|---|---|---|---|---|---|
| | Number | Percent | Amount | Percent | |
| Existing shareholders | | % | $ | % | $ |
| New investors | | | | | |
| Total | | 100% | | 100% | |

(1) Reflects 180 ordinary shares as equivalent to each ADS.

The foregoing tables and calculations are based on 1,353,350,744 ordinary shares outstanding as of June 30, 2022, and excludes:

- 79,056,617 ordinary shares issuable upon exercise of options outstanding as of June 30, 2022, at a weighted average exercise price of A$0.164 ($0.11) per share, of which options to purchase 31,065,275 ordinary shares were vested at a weighted average exercise price of A$0.14 ($0.04) per share; and
- 142,000,000 ordinary shares issuable upon exercise of warrants outstanding as of June 30, 2022 at a weighted average exercise price of A$0.06 ($0.04) per share, of which warrants to purchase 142,000,000 ordinary shares were vested at a weighted average exercise price of A$0.06 ($0.04) per share.

In addition, the foregoing calculations excludes shares issuable pursuant to future awards granted to our employees under the Employee Equity Plan or that might be granted to our directors. Under the ASX Listing Rules, we cannot, without the approval of our shareholders, subject to specified exceptions, issue, during any 12 month period, any equity securities, or other securities with rights to convert into equity, if the number of those securities exceeds 15% of the number of shares on issue at the commencement of that 12 month period (or 25% if shareholder approval is obtained at our annual general meeting. See “Description of Share Capital—No Shareholder Approval of Offering”) (“Placement Capacity”). Under ASX Listing Rules, we can issue up to 100 million ordinary shares or 10% of the ordinary shares outstanding at the completion of the IPO to employees under the Employee Equity Plan without reducing our Placement Capacity due to a shareholder approval obtained at our 2021 Annual General Meeting. Awards to our employees above such threshold under the Employee Equity Plan would reduce our Placement Capacity in the year in which such awards are granted. Awards under the Employee Equity Plan may be issued as ADSs based on the applicable ratio of ordinary shares to ADSs.

To the extent any outstanding options or warrants are exercised, there will be further dilution to new investors. If all of such outstanding options and warrants had been exercised as of June 30, 2022, the as-adjusted net tangible book value per ADS after this offering would be $ , and total dilution per ADS to new investors would be $ .

If the underwriters exercise their option to purchase additional ADSs in full:

- the percentage of ADS, or equivalent number of ordinary shares, held by existing shareholders will decrease to approximately % of the total number of ADSs, or the equivalent number of ordinary shares outstanding after this offering; and

- the number of ADSs, or equivalent number of ordinary shares, held by new investors will increase to , or approximately % of the total number of ADSs, or equivalent number of ordinary shares.

## Exchange Rate Information

The Australian Dollar is convertible into U.S. Dollars at freely floating rates. There are no legal restrictions on the flow of Australian Dollars between Australia and the United States. For your convenience, we have translated some Australian Dollar amounts into U.S. Dollar amounts using the Reserve Bank of Australia rate (the "RBA rate").

We make no representation that any Australian Dollar or U.S. Dollar amounts could have been, or could be, converted into U.S. Dollars or Australian Dollars, as the case may be, at any particular rate, the rates stated below, or at all.

The following table contains information for the RBA rate for the Australian Dollar into U.S. Dollars for the periods indicated.

| | At Period End ($) | Average Rate(1) ($) | High ($) | Low ($) |
|---|---|---|---|---|
| **Fiscal year ended June 30,** | | | | |
| 2017 | 0.7692 | 0.7542 | 0.7724 | 0.7202 |
| 2018 | 0.7391 | 0.7736 | 0.8121 | 0.7353 |
| 2019 | 0.7013 | 0.7153 | 0.7467 | 0.6840 |
| 2020 | 0.6863 | 0.6715 | 0.7065 | 0.5571 |
| 2021 | 0.7518 | 0.7492 | 0.7970 | 0.6895 |
| 2022 | 0.6889 | 0.7258 | 0.7615 | 0.6879 |
| **Month ended** | | | | |
| May 31, 2022 | 0.7187 | 0.7052 | 0.7241 | 0.6879 |
| June 30, 2022 | 0.6889 | 0.7030 | 0.7257 | 0.6889 |
| July 31, 2022 | 0.7007 | 0.6855 | 0.7007 | 0.672 |
| August 31, 2022 | 0.6902 | 0.6960 | 07.122 | 0.6858 |
| September 30, 2022 | 0.6502 | 0.6687 | 0.6874 | 0.6386 |

(1) For the fiscal years, determined by averaging Reserve Bank of Australia rate at the end of each day of each month during the fiscal year.

## Selected Consolidated Financial Data

The following tables set forth selected consolidated historical financial data as of, and for the periods ended on, the dates indicated. We have derived the statement of profit or loss data and the statement of financial position data for the years ended June 30, 2022 and 2021 from our audited consolidated financial included elsewhere in this prospectus. Our audited consolidated financial statements have been prepared in Australian Dollars and in accordance with International Financial Reporting Standards and interpretations issued by the International Accounting Standards Board. You should read this data together with our audited consolidated financial statements and related notes included elsewhere in this prospectus and the section in this prospectus entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results for any prior period are not indicative of our future results.

**Statement of Profit or Loss Data:**

| | Fiscal Year Ended June 30, | | |
|---|---|---|---|
| | 2022 | | 2021 |
| | $(1) | A$ | A$ |
| | (in thousands, except per share data) | | |
| Continuing operations: | | | |
| Revenue | $ 181 | $ 263 | $ — |
| Other income | 4,001 | 5,808 | 1,308 |
| Other gains and losses | (401) | (582) | 4,273 |
| Expenses | (18,903) | (27,440) | (14,465) |
| Loss before tax from continuing operations | (15,122) | $ (21,951) | $ (8,884) |
| Income tax benefit (expense) | 132 | 192 | 187 |
| Loss after tax from continuing operations | (14,990) | $ (21,759) | $ (8,697) |
| Discontinued operations: | | | |
| Loss for the year from discontinued operations | — | — | — |
| Loss for the year | (14,990) | (21,759) | (8,697) |
| Other comprehensive income: | | | |
| Exchange differences on translation of foreign operations | 735 | 1,067 | (1,169) |
| Total comprehensive profit (loss) attributable to the owners of the company | (14,255) | (20,692,224) | (9,866) |
| Earnings per share from continuing operations attributable to the owners of the company: | | | |
| Earnings per share, basic and diluted(2) | $ (0.01) | $ (0.02) | $ (0.01) |

**Statement of Financial Position Data:**

| | As of June 30, | | |
|---|---|---|---|
| | 2022 | | 2021 |
| | $(1) | A$ | A$ |
| | (in thousands) | | |
| Cash and cash equivalents | $23,123 | $33,565 | $28,499 |
| Trade and other receivables | 4,674 | 6,720 | 928 |
| Other current assets | 1,006 | 1,525 | 1,500 |
| Total current assets | 28,803 | 41,810 | 30,927 |
| Intangible assets and goodwill | 15,642 | 22,706 | 22,347 |
| Other non-current assets | 547 | 794 | 989 |
| Total non-current assets | 16,189 | 23,500 | 23,336 |
| Total assets | 44,992 | 65,310 | 54,263 |
| Total current liabilities | 2,312 | 3,356 | 2,361 |
| Total non-current liabilities | 3,473 | 5,042 | 4,305 |
| Total liabilities | 5,785 | 8,397 | 6,667 |
| Total equity attributable to owners of the company | 39,207 | 56,913 | 47,598 |

(1) The amounts have been translated into U.S. Dollars from Australian Dollars based upon the exchange rate as published by the Reserve Bank of Australia as of June 30, 2022. These translations are merely for the convenience of the reader and should not be construed as representations that the Australian Dollar amounts actually represent such U.S. Dollar amounts or could be converted into U.S. Dollars at such rate.

(2) See Note 2 to our audited consolidated financial statements included within our Annual Report on Form 20-F for the fiscal year ended June 30, 2022, which is incorporated by reference in this prospectus, for an explanation of the method used to compute basic and diluted earnings per share.

## Management's Discussion and Analysis of Financial Condition and Results of Operations

*You should read the following discussion and analysis of our financial condition and results of operations, presented in Australian Dollars (A$), together with our audited consolidated financial statements and the related notes and other financial information included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties.*

*You should review the "Risk Factors" section of this prospectus for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

### Overview

We are a clinical-stage biopharmaceutical company developing a pipeline of novel, allosteric ion channel modulators focused on transforming the lives of patients suffering from serious and underserved central nervous system ("CNS") disorders. 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 important ion channel that serves as a key driver of emotional response and cognitive performance and its well-understood biology has garnered significant attention as a pharmacological target for cognitive deficits. Utilizing our ion channel expertise, we are developing orally active small molecule negative allosteric modulators ("NAMs") and positive allosteric modulators ("PAMs") of the α7 receptor to treat anxiety-related and cognitive disorders, respectively.

We are advancing our lead product candidate, BNC210, an oral proprietary selective NAM of the α7 receptor, for the acute treatment of Social Anxiety Disorder ("SAD") and chronic treatment of Post-Traumatic Stress Disorder ("PTSD"). We have initiated our Phase 2 PREVAIL trial for BNC210 for the acute treatment of SAD and currently anticipate reporting topline data by the end of 2022. We have initiated our Phase 2b ATTUNE trial, a randomized, placebo-controlled study to evaluate BNC210 for the treatment of PTSD and we expect to report topline data in mid 2023. Our expertise and approach have been validated through our June 2014 research collaboration and license agreement (as amended, the "2014 Merck License Agreement") with Merck Sharp & Dohme Corp., a wholly owned subsidiary of Merck & Co., Inc., Kenilworth NJ, USA ("Merck") for our α7 receptor Positive Allosteric Modulator (PAM) program, which targets a receptor that has garnered significant attention for treating cognitive deficits. This partnership enables us to maximize the value of our ion channel and chemistry platforms and develop transformative medicines for patients suffering from cognitive disorders such as Alzheimer's disease.

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 Global Market in 2021. 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, 2022, our operations have been financed primarily by aggregate net proceeds of A$199.8 million from the sale and issuances of our equity, A$22.6 million of borrowings, A$34.1 million in the form of an upfront payment, research funding and a milestone payment from the 2014 Merck License Agreement, and A$77.5 million from Australian research and development credits and government grants and assistance. Since inception, we have had significant operating losses. Our net loss after tax from continuing operations was A$21.8 million and A$8.7 million for the years ended June 30, 2022 and 2021, respectively. As of June 30, 2022, we had an accumulated deficit of A$173.3million and cash and cash equivalents of A$33.6 million.

Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our trade and other payables. We expect to continue to incur net losses for the foreseeable future, and we expect our research and development expenses, and our administrative and other expenses will continue

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

Based upon our current operating plan, we believe that the net proceeds from this offering together with our existing cash and cash equivalents, will be sufficient to continue funding our development activities through the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured.

**Impact of COVID-19**

In March 2020, the WHO declared the COVID-19 outbreak a pandemic. In order to mitigate the spread of COVID-19, governments have imposed unprecedented restrictions on business operations, travel and gatherings, resulting in a global economic downturn and other adverse economic and societal impacts. We have considered the impact of COVID-19 on our operations and financial performance. Operations for the fiscal years ended June 30, 2022 and 2021 were not materially affected by the COVID-19 pandemic. Our Phase 2b ATTUNE clinical trial for BNC210 in patients with PTSD and our Phase 2 PREVAIL clinical trial for BNC210 in patients with SAD started on time in the United States during 2021 and 2022, respectively, and have not been affected by the COVID-19 pandemic.

However, the impact of related responses and disruptions caused by the COVID-19 pandemic may result in difficulties or delays in completing our clinical trialsdue to difficulties in enrolling patients, resulting in the incurrence of unforeseen costs as a result of delays in completing the trial. We are continuing to work closely with our clinical partners and have taken steps as necessary to allow for adjustments in the clinical trial protocol, should they be required due to restrictions that may be imposed during the COVID-19 pandemic.

The COVID-19 pandemic and its impacts continue to evolve. We cannot predict the scope and severity of any further disruptions as a result of COVID-19 or their impacts on us, but business disruptions for us or any of the third parties with whom we engage, including the collaborators, contract organizations, manufacturers, suppliers, clinical trial sites, regulators and other third parties with whom we conduct business could materially and negatively impact our ability to conduct our business in the manner and on the timelines presently planned. The extent to which the COVID-19 pandemic may continue to impact our business and financial performance will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the scope and duration of the pandemic, the extent and effectiveness of government restrictions and other actions, including relief measures, implemented to address the impact of the pandemic, and resulting economic impacts. We are unable to determine the extent of the impact of the pandemic on our clinical trials, operations and financial condition going forward. These developments are highly uncertain and unpredictable and may materially adversely affect our financial position and results of operations.

**Licenses and Collaborations**

In June 2014, we entered the 2014 Merck License Agreement to develop compounds targeting cognitive dysfunction associated with Alzheimer’s disease and other central nervous system conditions. Pursuant to the 2014 Merck License Agreement, we received upfront payments totaling $20 million, and another $10 million in February 2017 when the first compound from the collaboration entered Phase 1 clinical trials and we are eligible to receive up to an additional $465 million in milestone payments for achievement of certain development and

commercial milestones. Further, Merck is obligated to pay us tiered royalties in the mid single digit to low sub-teen double digit percentage range on net sales of the licensed products, subject to reduction upon certain events.

In November 2020, we entered into an IP license agreement (the "Carina Biotech License") with Carina Biotech. Pursuant to the Carina Biotech License, we are eligible to receive up to A$118 million in certain development, regulatory and commercial milestone payments if Carina Biotech fully develops and markets the new therapy. Carina Biotech is also obligated to pay us royalties on its net sales of licensed products, on a country-by-country and product-by-product basis, ranging from the low single digits to the mid-single digits, subject to certain specified deductions. Royalties are payable until the later of expiration of all licensed patents covering the licensed products, or expiration of all data exclusivity with respect to the licensed product. If Carina Biotech enters into one or more sublicensing agreements relating to the licensed product, we are eligible to receive a percentage of sublicensing revenues. To date, no payments have been made pursuant to the Carina Biotech License.

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 single digit royalties on the net sales of BNC210, if commercialized.

**Components of Operating Results from Continuing Operations**

***Income***

Our income consists of revenue, other income and other gains and losses.

*Revenue*

Our primary source of revenue historically has been upfront and milestone payments with respect to out-licensing payments and research funding from Merck and CTx. To date, we have not had any products approved for sale and, therefore, have not generated any product revenue.

*Other Income*

Our other income includes (i) income related to the Australian Government's Research and Development Tax Incentive program; (ii) interest income earned on our bank accounts; and (iii) sub-lease income on part of our prior leased office facility in Adelaide, Australia, which concluded July 2021.

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.

*Other Gains and Losses*

Other gains and losses include the changes in the fair value of our contingent consideration liability, and net realized and unrealized foreign exchange gains and losses.

***Expense***

Our expenses since inception have consisted primarily of research and development expenses, 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;
- expenses incurred under agreements with third parties, including CROs that conduct research, preclinical activities and clinical trials on our behalf as well as CMOs that manufacture our product candidates for use in our preclinical studies and clinical trials and perform CMC activities; and
- filing and maintenance of patents and intellectual property rights, including payment to third parties for assignment of patent rights and licensing fees and milestone payments incurred under product license agreements where no alternative future use exists.

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 of our direct research and development expenses in the years ended June 30, 2022 and 2021 were on BNC210 and consisted primarily of external costs, such as consultants, third-party contract organizations that conduct research and development activities on our behalf, costs related to production of preclinical and clinical materials, including fees paid to contract manufacturers, 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 of 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 enrollment and completion of our ongoing Phase 2b ATTUNE clinical trial for BNC210 in patients with PTSD and our planned Phase 2 PREVAIL trial for BNC210 for the acute treatment of SAD, and any clinical trials for BNC210 or future product candidates;
- 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 FDAs, regulatory authorities in Europe, or other regulatory agencies, of the IND applications, clinical trial applications and/or other regulatory filings for BNC210, our other current product candidates and any future product candidates;
- expansion and maintenance of a workforce of experienced scientists and others to continue to develop our product candidates;
- successful application for and receipt of marketing approvals from applicable regulatory authorities;
- obtainment and maintenance of regulatory exclusivity for our product candidates;
- arrangements with third-party manufacturers for, or establishment of, commercial manufacturing capabilities;
- establishment of sales, marketing and distribution capabilities and successful launch of commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effective competition with other therapies;
- obtainment and maintenance of coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;
- obtainment, maintenance, enforcement, defense and protection of our rights in our intellectual property portfolio;
- avoidance of infringement, misappropriation or other violations with respect to others' intellectual property or proprietary rights; and
- maintenance of a continued acceptable safety profile of our products following receipt of any marketing approvals.

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

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

*Administration Expenses*

Our administration expenses consist primarily of personnel costs, consultancy fees and director fees. We expect our administration expenses to increase over the next several years to support expanded research and development activities and operating as a U.S. public company, including costs of additional personnel and increased costs related to additional investor relations activities.

*Occupancy Expenses*

Our occupancy expenses include the costs relating to our headquarters in Adelaide, Australia, including lease depreciation, maintenance and incidental costs. In June 2021, we moved to a new smaller leased office space in Adelaide and, as a result, our near-term, future occupancy expenses are expected to decline.

*Compliance Expenses*

Our compliance expenses include costs relating to audit, tax and regulatory compliance, legal fees and insurance. We expect our compliance expenses to increase going forward in connection with being a public company in the United States, with increased fees to outside consultants, lawyers and accountants, and increased costs associated with being a U.S. public company, such as expenses related to services associated with maintaining compliance with Nasdaq listing rules and SEC requirements, director and officer insurance premiums and investor relations costs.

*Finance Expenses*

Our finance expenses on an ongoing basis consist primarily of interest expense on the finance lease liability relating to the lease of our headquarters in Adelaide, Australia. In April 2021 we repaid in full our U.S.-dollar denominated borrowings, and our equipment mortgage loans.

*Foreign Currency Exchange*

Our financial results are reported in Australian Dollars. A substantial portion of our operating expenses and revenues are denominated in the U.S. dollar. During the years ended June 30, 2022 and 2021, we have managed our exchange rate exposure principally by purchasing currencies and 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. See “Quantitative and Qualitative Disclosures about Market Risk” for more information.

**Results of Operations**

***Comparison of Fiscal Years ended June 30, 2022 and 2021***

| | Fiscal Year ended June 30, | | Increase (Decrease) | |
|---|---|---|---|---|
| | 2022 | 2021 | Amount | Percent |
| | (in thousands) | | | |
| | A$ | A$ | A$ | % |
| **Continuing Operations** | | | | |
| Revenue | 263 | — | 263 | 100 |
| Other income | 5,808 | 1,308 | 4,500 | 344 |
| Other gains and losses | (582) | 4,273 | (4,855) | (114) |
| **Expenses** | | | | |
| Research and development expenses | (15,999) | (5,762) | 10,237 | 178 |
| Administration expenses | (7,398) | (4,374) | 3,024 | 69 |
| Occupancy expenses | (262) | (1,271) | (940) | (148) |
| Compliance expenses | (3,737) | (1,614) | 2,123 | 132 |
| Finance expenses | (44) | (1,444) | (1,400) | (97) |
| **Loss before tax** | (21,951) | (8,884) | 13,067 | 148 |

*Revenue*

The increase of A$0.3 million in our revenue is due to licensing revenue received from CTx in the fiscal year ended June 30, 2022 whereas there was no licensing revenue received in fiscal year June 30, 2021.

*Other Income*

Our other income for the fiscal year ended June 30, 2022 increased by A$4.5 million, or 344%, to A$1.3 million as compared to the fiscal year ended June 30, 2021. This increase was due to an increase in government research and development incentives of A$4.8 million resulting from (i) an increase in qualifying research and development expenses for the Australian research and development credits, offset by a decrease in sublease rent received of A$0.2 million, as the sublease of our previous premises ceased on July 12, 2021 and (ii) a decrease in government COVID-19 assistance of A$0.1 million, as no government assistance was received during 2022.

*Other Gains and Losses*

Other gains and losses include the changes in the fair value of our contingent consideration liability, and net realized and unrealized foreign exchange gains and losses. The decrease of A$4.9 million, or 114%, to loss of A$0.6 million for the fiscal year ended June 30, 2022 as compared to a gain for the fiscal year ended June 30, 2021 of A$4.3 million, was due to a A$4.2 million decrease in net gains arising from the change in the fair value of contingent consideration liability for fiscal year ended June 30, 2021. There was a net gain which resulted from using the inputs from the Carina licensing agreement which was signed during November 2020 and the USD exchange rate at June 30, 2021 to calculate the contingent consideration liability, whereas the net loss in fiscal year ended June 30, 2022 resulted from using the USD exchange rate at June 30, 2022 and offset by a A$0.7 million decrease in realized and unrealized net foreign exchange gains and losses.

*Research and Development Expenses*

Our research and development activities in the fiscal years ended June 30, 2022 and June 30, 2021, were principally focused on the advancement of BNC210. The increase in the fiscal year ended June 30, 2022 of A$10.2 million, or 178%, to A$16.0 million, as compared to the fiscal year ended June 30, 2021 was primarily due an increase in expenditure associated with the PTSD ATTUNE clinical trial which started during July 2021 and the SAD PREVAIL clinical trial which started during January 2022.

*Administration Expenses*

The increase in administration expenses in the fiscal year ended June 30, 2022 of A$3.0 million, or 69%, to A$7.4 million, as compared to the fiscal year ended June 30, 2021 was due to a A$1.5 million increase in share-based compensation expense, one-off expense during the fiscal year ended June 30, 2022 for fees paid to external consultants of A$0.7 million for the proposed capital distribution (representing an economic interest in the net after tax royalty payments (if any), received by us under our exclusive Research Collaboration and License Agreement with Merck Sharp & Dohme Corp. relating to BNC375 and related compounds) that did not proceed, an increase in the Executive Chairman consultancy fee of A$0.4 million and an increase in consultant fees, salary and related costs of A$0.4 million.

*Occupancy Expenses*

The decrease in occupancy expenses in the fiscal year ended June 30, 2022 of A$0.9 million, or 148%, to A$0.3 million, as compared to the fiscal year ended June 30, 2021 was primarily due to our move to a new leased office premises during May 2021.

*Compliance Expenses*

The increase in compliance expenses in the fiscal year ended June 30, 2022 of A$2.0 million, or 132%, to A$3.7 million, as compared to the fiscal year ended June 30, 2021 was primarily due to an increase insurance

expense as result of our Nasdaq listing of A$1.2 million, an increase in audit fees of $0.9 million due to initial public offering ("IPO") audit requirements (A$0.6 million) and PCAOB and Australian statutory audit requirements in the fiscal year ended 2022 compared to only statutory audit requirement in the fiscal year ended 2021 (A$0.3 million), offset by a net decrease in other compliance expenses of A$0.1 million.

*Finance Expenses*

The decrease in finance expenses in the fiscal year ended June 30, 2022 of A$1.4 million, or 97%, to A$0.04 million, as compared to the fiscal year ended June 30, 2021 is due to bank loan and equipment loans being full repaid during April 2021.

**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, 2022, we had cash and cash equivalents of A$33.6 million and an accumulated deficit of A$173.3 million.

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

***Comparison of Fiscal Years ended June 30, 2022 and 2021***

| | Fiscal Year ended June 30, | |
|---|---|---|
| | 2022 | 2021 |
| | (in thousands) | |
| | A$ | A$ |
| Net cash used by operating activities | (21,755) | (7,539) |
| Net cash used by investing activities | 622 | (80) |
| Net cash generated (used by) financing activities | 26,995 | 31,554 |
| Net increase (decrease) in cash and cash equivalents | 5,862 | 23,935 |

*Operating Activities*

The A$14.2 million increase in net cash used in operating activities from A$7.5 million for fiscal year ended June 30, 2021 to A$21.7 million for the fiscal year ended June 30, 2022 reflects a A$22.0 million increase in net cash used in continuing operating activities partially offset by a A$6.8 million decrease in interest and bank fees paid due to bank loan and equipment loans being fully repaid during April 2021. See Note 33 to our audited consolidated financial statements included within our Annual Report on Form 20-F for the fiscal year ended June 30, 2022, which is incorporated by reference in this prospectus, for additional information on our discontinued operations.

*Investing Activities*

Investing activities in the fiscal year ended June 30, 2022 included the receipt of A$0.4 million for a bank guarantee that was required for our previous office lease and receipt ofA$-.2 million relating to proceeds from disposals of plant and equipment. See Note 33 to our audited consolidated financial statements included within our Annual Report on Form 20-F for the fiscal year ended June 30, 2022, which is incorporated by reference in this prospectus, for additional information on our discontinued operations.

*Financing Activities*

Financing activities in the fiscal year ended June 30, 2022 included net proceeds of A$27.2 million from the sale and issuance of shares and A$0.2 million of repayment of the principal elements of lease payments. Notably,

in April 2021 we repaid in full our outstanding U.S. dollar denominated borrowings and equipment mortgage loans. Financing activities in the fiscal year ended June 30, 2021 included A$43.4 million of net proceeds from the sale and issuance of shares offset by A$11.2 million of repayment of borrowings and principal elements of lease payments.

*Funding Requirements*

Any product candidates we may develop may never achieve commercialization and we anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development expenses and our general and administrative expenses will continue to increase. As a result, until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses (including share based compensation); costs related to third-party clinical research, nonclinical 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 on our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our current operations through the next 12 months. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We will continue to require additional financing to advance our current product candidates through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. We will continue to seek funds through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders, including investors in this offering, will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

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

- the scope, progress, results and costs of independently researching and developing any of our product candidates and conducting preclinical studies and clinical trials;
- the timing, receipt and amount of milestone payments, if any, from Merck under the 2014 Merck License Agreement to develop and commercialize compounds targeting cognitive dysfunction associated with Alzheimer's disease and other central nervous system conditions;
- the timing and receipt of proceeds on the exercise of warrants and share options, if at all exercised;
- the number, indications and characteristics of the product candidates we pursue;
- the cost of manufacturing our approved drugs, if any;
- the cost of commercialization activities;

- our ability to maintain existing collaborations and to establish new collaborations, licensing or other arrangements and the financial terms of such agreements; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including litigation costs and the outcome of such litigation.

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

The net proceeds from this offering will not be sufficient to fund our operations through successful development and commercialization of all our potential product candidates. If we were unable to obtain additional financing, 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.”

**Critical Accounting Policies and Significant Management Estimates**

Our management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with IFRS. The preparation of our consolidated financial statements requires us to make estimates and judgments that can affect the reported amounts of assets, liabilities, revenues and expenses, as well as the disclosure of contingent assets and liabilities at the date of our financial statements. We analyze our estimates and judgments, and we base our estimates and judgments on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results may vary from our estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management’s judgments and estimates.

*Impairment of Goodwill and Other Intangible Asset*

We assess annually, or whenever there is a change in circumstances, whether goodwill or other intangible assets may be impaired. Determining whether goodwill and other intangible assets are impaired requires an estimation of the value in use of the cash generating unit (drug discovery and development) to which goodwill and other intangible assets have been allocated. The value in use calculation is judgmental in nature and requires us to make a number of estimates including the future cash flows expected to arise from the cash generating unit based on observable market comparables for products and product candidates within the cash generating unit and over a period covering drug discovery, development, approval and marketing as well as a suitable discount rate in order to calculate present value. The cash flow projections are further weighted based on the observable market comparable probability of realizing projected milestone and royalty payments. When the carrying value of the cash generating unit exceeds its recoverable amount, the cash generating unit is considered impaired and is written down to its recoverable amount, with the impairment loss recognized in the consolidated statement of profit or loss and other comprehensive income. A detailed valuation was performed as of June 30, 2022, and 2021 and each computed fair value of our cash generating unit was in excess of the carrying amount. As a result of this evaluation, we determined that no impairment of goodwill or other intangible assets existed at June 30, 2022 and 2021.

*Fair Value Recognized on Business Combinations—Contingent Consideration*

Part of the consideration for a past acquisition of Eclipse Therapeutics Inc. (“Eclipse”) which included the acquisition of BNC101, a legacy oncology asset, included potential cash earn-outs based on achieving late-stage development success or partnering outcomes if the company is acquired. This liability is recorded at fair value

and includes a number of significant estimates including adjusted revenue projections, probability of such projections and a suitable discount rate to calculate present value. Due to changes in the projected inputs, being the timing and quantum of expected cash outflow, the liability has increased by A$0.9 million to A$2.7 million, with the increase being recognized in Other Gains and Losses in the Consolidated Statement of Profit or Loss and Other Comprehensive income for the fiscal year ended June 30, 2022. International Financial Reporting Standards required that in a “business combination” ( our acquisition of Eclipse) any contingent consideration liability at acquisition date needs to be recorded at the fair value and subsequent changes in the fair value are recognized in profit or loss, but any contingent assets at acquisition date are not allowed to be recorded. We have a contingent asset (the expected payments to be received from Carina Biotech) at June 30, 2022 which is greater than the contingent consideration liability.

**Recent Accounting Pronouncements**

Refer to Note 2, “Summary of Significant Accounting Policies,” in the accompanying notes to our financial statements for the years ended June 30, 2022, and 2021 included within our Annual Report on Form 20-F for the fiscal year ended June 30, 2022, which is incorporated by reference in this prospectus, for a discussion of recent accounting pronouncements.

**Off-Balance Sheet Arrangements**

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

**Quantitative and Qualitative Disclosures about Market Risk**

*Foreign Currency Risk*

Although our financial results are reported in Australian dollars, a portion of our operating expenses and any future milestone payments under the 2014 Merck License Agreement will be denominated in the U.S. dollar.

The following table summarizes our exposure to foreign currency risk (all of which are risks against the U.S. dollar), expressed in Australian dollars as at June 30, 2022 and 2021:

| | June 30, | |
|---|---|---|
| | 2022 | 2021 |
| | (in thousands) | |
| | A$ | A$ |
| ***Monetary items*** | | |
| Cash and cash equivalents | 17,786 | 625 |
| Trade and other payables | (1,298) | (672) |
| Borrowings | — | — |
| Contingent consideration liability | (2,699) | (1,762) |
| Total monetary items | (13,789) | (1,810) |
| ***Non-monetary items*** | | |
| Goodwill | 5,921 | 5,454 |
| Other intangible assets | 9,838 | 9,946 |
| Deferred income liability | (1,799) | (1,842) |
| Total non-monetary items | 13,960 | 13,558 |
| **Total Monetary and Non-Monetary Items** | 27,749 | 11,746 |

The following table sets forth a sensitivity analysis of our exposure to a 10% increase and decrease in the Australian dollar against the U.S. dollar. We use 10% for the sensitivity rate used when reporting foreign currency risk internally to key management personnel, which represents management’s assessment of the

reasonably possible change in foreign currency rates. The sensitivity analysis below includes only outstanding foreign currency denominated monetary items and adjusts their translation at the year-end for a 10% change in foreign currency rates. A positive number below indicates an increase in profit or equity where the Australian dollar strengthens 10% against the U.S. dollar. For a 10% weakening of the Australian dollar against the U.S. dollar, there would be a comparable impact on the profit or equity with the balances being the opposite.

| | Fiscal Year ended June 30, | |
|---|---|---|
| | 2022 | 2021 |
| | (in thousands) | |
| | A$ | A$ |
| Profit or loss(i) | 1,797 | (223) |
| Equity(ii) | 18 | 3 |

(i) This is attributable to the exposure to outstanding U.S. dollar net monetary assets at the end of the fiscal year.

(ii) This is attributable to the exposure to outstanding U.S. dollar net monetary assets at the end of the reporting period in the subsidiaries which are denominated in the U.S. dollar and reflected in the foreign currency translation reserve.

Our sensitivity to foreign currency has decreased mainly due to repayment in full during April 2021 of our U.S.-dollar denominated borrowing and a lower contingent consideration liability.

*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 and 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. If our costs become subject to significant inflationary pressures, this could harm our business, financial condition, and operating results.

**Implication of Being an Emerging Growth Company**

We are an “emerging growth company,” (“EGC”) as defined in the JOBS Act. As an EGC under the JOBS Act, we may delay the adoption of certain accounting standards until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for EGCs include an exemption from the requirement to provide an auditor’s report on internal controls over financial reporting

pursuant to Section 404(b) of the Sarbanes-Oxley Act, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements.

We may remain classified as an EGC until the end of the fiscal year following the fifth anniversary of this offering, although if the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of June 30 of any year before that time, or if we have annual gross revenues of $1.235 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We would also cease to be an EGC if we issue more than $1.0 billion of non-convertible debt over a three-year period.

**Implications of Being a Foreign Private Issuer**

We are also considered a "foreign private issuer," as defined in Rule 405 under the Securities Act of 1933, as amended. In our capacity as a foreign private issuer, we are exempt from certain rules under the Exchange Act, that impose certain disclosure obligations and procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and the rules under the Exchange Act with respect to their purchases and sales of our ordinary shares or the ADSs. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. In addition, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information.

We may take advantage of these exemptions until such time as we are no longer a foreign private issuer. We would cease to be a foreign private issuer at such time as more than 50% of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: (1) the majority of our executive officers or directors are U.S. citizens or residents, (2) more than 50% of our assets are located in the United States or (3) our business is administered principally in the United States.

As both an emerging growth company and a foreign private issuer, we have taken advantage of certain reduced disclosure and other requirements in this prospectus and may elect to take advantage of other reduced reporting requirements in future filings. Accordingly, the information contained herein or that we provide shareholders may be different than the information you receive from other public companies in which you hold equity securities.

# Business

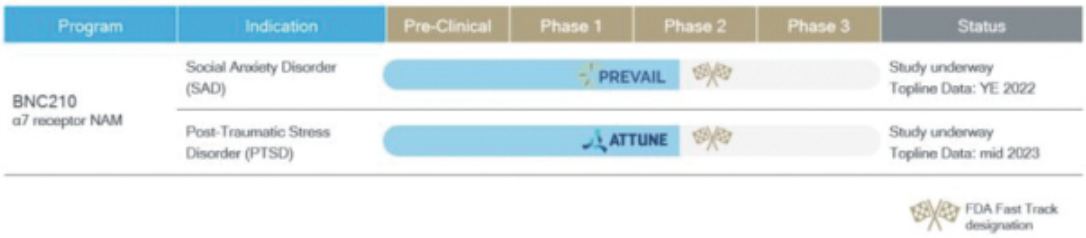
## Overview

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") and positive allosteric modulators ("PAMs") of the α7 receptor to treat anxiety and stressor-related disorders and cognitive dysfunction, respectively.

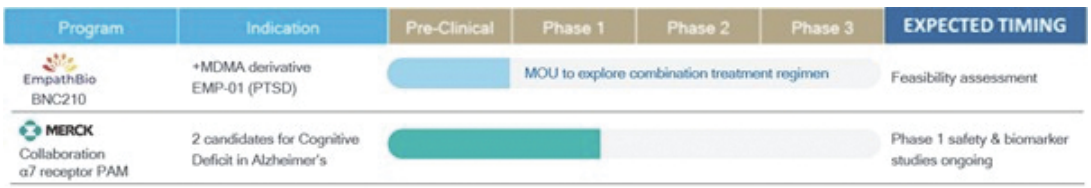
We are advancing our lead product candidate, BNC210, an oral, proprietary, selective NAM of the α7 receptor, for the acute treatment of Social Anxiety Disorder ("SAD") and chronic treatment of Post-Traumatic Stress Disorder ("PTSD"). There remains a significant unmet medical need for the over 22 million patients in the United States alone suffering from SAD and PTSD. Current pharmacological treatments include certain antidepressants and benzodiazepines, and there have been no new FDA approved therapies in these indications in nearly two decades. These existing treatments have multiple shortcomings, such as a slow onset of action of antidepressants, and significant side effects of both classes of drugs. 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 have initiated our Phase 2 PREVAIL trial for BNC210 for the acute treatment of SAD by the end of 2021 and currently anticipate reporting topline data by the end of 2022. We have initiated our Phase 2b ATTUNE trial, a randomized, placebo-controlled study to evaluate BNC210 for the treatment of PTSD and we expect to report topline data in mid-2023. Our expertise and approach have been validated through our June 2014 research collaboration and license agreement (as amended, the "2014 Merck License Agreement") with Merck Sharp & Dohme Corp., a wholly owned subsidiary of Merck & Co., Inc., Kenilworth NJ, USA ("Merck") for our α7 receptor PAM program, which targets a receptor that has garnered significant attention for treating cognitive deficits. This partnership enables us to maximize the value of our ion channel and chemistry platforms and develop transformative medicines for patients suffering from cognitive disorders such as Alzheimer's disease.

Below is a summary of our non-partnered pipeline, which shows the current status and expected topine data:




Below is a summary of the status of the programs under our collaboration relationships:



**BNC210**

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

- fast acting 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; and
- no impairment of motor coordination.

We have administered BNC210 in approximately 400 subjects across 12 completed clinical trials, including healthy volunteers, elderly patients with agitation and patients with Generalized Anxiety Disorder ("GAD") and PTSD. We have observed BNC210 to be generally well tolerated in the trials to date following both acute and chronic dosing. Further, in our clinical trials in GAD patients and in panic-induced healthy subjects, we have observed three key results:

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

We have designed and developed a novel, proprietary tablet formulation of BNC210 which has shown differentiated pharmacokinetic properties in clinical trials. BNC210 tablet has demonstrated rapid oral absorption characteristics in clinical trials making it ideal for acute, or on demand, treatment of SAD. Furthermore, the tablet formulation is intended to provide patients the convenience of taking BNC210 with or without food in the outpatient setting. In previous clinical trials (using 900 mg twice daily dosing similar to that being used in the ATTUNE Study), the tablet formulation achieved a target blood exposure ranging from 33-57 mg.h/L, which exceeds the blood exposure of approximately 25 mg.h/L which our pharmacometric analysis predicted as likely to show clinically meaningful benefit for patients suffering from PTSD. We are using this tablet formulation in our ongoing Phase 2b ATTUNE clinical trial for patients with PTSD Phase 2 PREVAIL trial for patients with SAD. We anticipate topline data for our SAD trial by the end of 2022 and for our PTSD trial in mid-2023. We have received Fast Track designation from the FDA for our PTSD and SAD programs. In addition, we have a memorandum of understanding with EmpathBio for preclinical feasibility studies to evaluate a combination of EMP-01, a 3,4-methylenedioxymethamphetamine ("MDMA") derivative and BNC210 as an adjunct to behavioral therapy for the treatment of PTSD.

**Additional Programs**

***α7 Receptor PAM Program with Merck***

In June 2014, we entered into the 2014 Merck License Agreement to develop α7 receptor PAMs targeting cognitive dysfunction associated with Alzheimer's disease and other central nervous system conditions. Under the 2014 Merck License Agreement, Merck funded certain research and development activities on a full-time equivalent ("FTE") basis pursuant to a research plan. Merck funds current and future research and development activities, including clinical development and worldwide commercialization of any products developed from the collaboration.

We received upfront payments totaling $20 million, which included funding for FTEs for the first twelve months, and another $10 million in February 2017 when the first compound from the collaboration initiated Phase 1 clinical trials, and we are eligible to receive up to an additional $465 million in milestone payments for achievement of certain development, regulatory and commercial milestones. The Merck collaboration currently includes two candidates which are PAMs of the α7 receptor that are in early-stage Phase 1 safety and biomarker clinical trials for treating cognitive impairment. The first compound has completed Phase 1 safety clinical trials in healthy subjects and there are ongoing biomarker studies. In 2020 a second molecule that showed an improved potency profile in preclinical animal models was advanced by Merck into Phase 1 clinical trials. Merck controls the clinical development and worldwide commercialization of any products developed from the collaboration and therefore we cannot predict whether or when we might achieve any milestone payments under the collaboration or estimate the full amount of such payments, and we may never receive any such payments. Further, we are subject to limited information rights under the 2014 Merck License Agreement. As such, we are dependent on Merck to provide us with any updates related to clinical trial results, serious adverse events and ongoing communications with FDA or other regulatory agencies related to these programs, which Merck may provide or withhold in its sole discretion, and as a result we may not be able to provide material updates on a timely basis or at all with respect to these programs.

***Our Early-Stage CNS Assets***

Our CNS pipeline includes two earlier stage small molecule discovery programs targeting ion channels and represents additional opportunities for future clinical programs and partnering. These programs are at a similar stage to the stage at which the α7 receptor PAM program was licensed under the 2014 Merck License Agreement, although there is no assurance that we will be able to enter into a license or collaboration agreement with respect to these programs. The first of these programs has developed two patented series of small molecule Kv3.1/3.2 potassium channel activators for the potential treatment of cognitive deficits and negative symptoms/social withdrawal in schizophrenia and autism spectrum disorders. The second program has developed three patented series of small molecule inhibitors with functional selectivity for Nav1.7 and Nav1.8 voltage gated sodium ion channels for the potential treatment of chronic pain without the liability of addiction associated with opioid treatment.

***Legacy Oncology Programs***

We have a portfolio of legacy clinical-stage oncology programs targeting cancer stem cells (BNC101) and tumor vasculature (BNC105) that we have progressed through external funding for clinical trials and out-licensing to capture future value for our shareholders. Our first legacy oncology program is BNC101, a novel humanized monoclonal antibody that targets LGR5, a cancer stem cell receptor highly overexpressed in most solid tumors. In November 2020, we exclusively licensed BNC101 to Carina Biotech for the development of chimeric receptor antigen T-cell (“CAR-T”) therapeutics in return for milestones and royalties. Our second legacy oncology program, BNC105, is a novel vascular tubulin polymerization inhibitor agent for treatment of cancer, which disrupts the blood vessels that nourish tumors. We plan to advance these oncology programs only through existing and potentially new partnerships.

**Our Team**

We have assembled a strong management team of experts complemented by an international board of directors with deep scientific and clinical expertise in CNS drug discovery and development and expertise in strategy and business development. The management team is led by Errol B. De Souza, Ph.D., our Executive Chairman, who has over 30 years of substantive experience as an executive in the biopharmaceutical industry, having founded Neurocrine Biosciences, served as President and CEO of several U.S.-based public and private biopharmaceutical companies including Biodel, Synaptic Pharmaceutical Corp., Archemix and Neuropore Therapeutics, and led large Research & Development organizations (Head of CNS Diseases at DuPont Merck and Head of US R&D at Aventis Pharmaceuticals) in global pharmaceutical companies. We have assembled an

experienced management and scientific team with a track record of success in the field of CNS drug development. Members of our management team have held senior positions at Deloitte Touche Tohmatsu, New World Bio Limited, Apeiron Investment Group, Circumvent Pharmaceuticals and RBC Capital Markets. We believe that the breadth of experience and successful track record of our senior management, combined with our established relationships with leaders in the industry and medical community, provide us with unique insights into drug development for the treatment of CNS disorders. We have also been supported by a leading syndicate of investors, including BVF Partners L.P. ("BVF") and Apeiron Investment Group Ltd.

**Our Strategy**

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

- Advance our lead product candidate, BNC210, through clinical development and to commercialization, if approved, for the acute treatment of patients with SAD. BNC210 is an oral, proprietary, selective NAM of the α7 receptor designed to normalize the neurotransmitter imbalance and address anxiety and stressor-related disorders. Based on the favorable rapid absorption profile of our novel tablet formulation and evidence of anti-anxiety effect from our prior Phase 2 GAD trial, we believe there is a strong clinical and translational rationale to advance BNC210 for the acute treatment of patients with SAD, which we believe now has a defined clinical and regulatory pathway based on the FDA's prior support of using a public speaking challenge and the Subjective Units of Distress Scale ("SUDS") as a registrational endpoint. In October 2021, we received FDA clearance for our investigational new drug application ("IND") to conduct our Phase 2 PREVAIL trial with BNC210 for the acute treatment of SAD. We have received Fast Track designation from the FDA for BNC210 for the acute treatment of SAD and other anxiety-related disorders. We have initiated our PREVAIL trial with BNC210 for the acute treatment of SAD and we currently expect to report topline data by the end of 2022.
- Progress BNC210 through clinical development and to commercialization, if approved, in patients with PTSD. Supported by data observed in our previous Phase 2 RESTORE trial for PTSD using a liquid suspension formulation of BNC210 in July 2021, we initiated our Phase 2b ATTUNE clinical trial with the novel tablet formulation of BNC210. Our Phase 2b ATTUNE trial is a randomized, double-blind, placebo-controlled clinical trial evaluating BNC210 monotherapy treatment in approximately 200 PTSD patients over a 12-week treatment period. We have received Fast Track designation from the FDA for our PTSD program and expect to report topline data in mid-2023.
- Expand indication potential for BNC210 to other acute and chronic anxiety and stressor-related disorders. Based on what we believe is the novel mechanism of action of BNC210, data observed in approximately 400 subjects to date in 12 completed clinical trials that BNC210 has been generally well tolerated and the broad utility of negative allosteric modulators of the α7 receptor, we believe BNC210 has the potential to address a wide-range of anxiety and stressor-related CNS disorders beyond acute treatment of SAD and chronic treatment of PTSD. We intend to continue evaluating BNC210's potential for acute and chronic treatment of additional anxiety indications such as GAD, panic disorder and chronic treatment of SAD.
- Build a commercialization infrastructure in the United States for BNC210. We have retained global development and commercialization rights to BNC210 and intend to maximize its commercial opportunity across global markets. We currently intend to build a focused commercial organization in the United States to market BNC210, if approved. Outside the United States, we will evaluate strategic opportunities to maximize the commercial potential of BNC210 with collaborators whose development and commercial capabilities complement our own.
- Maximize the potential of our CNS programs and legacy oncology assets through selective partnerships and licensing. We have generated a series of product candidates that may have transformative potential across a range of CNS indications through our expertise in ion channels and, specifically, α7 receptors.

We have an ongoing collaboration with Merck for our α7 receptor PAM program to treat patients with cognitive impairment associated with Alzheimer's disease and other CNS conditions. In addition, we have a memorandum of understanding with EmpathBio to conduct preclinical feasibility studies to evaluate a combination of EMP-01, an MDMA derivative, and BNC210 as an adjunct to behavioral therapy, for the treatment of PTSD. We have also used our expertise in ion channel biology to identify multiple series of Nav1.7/1.8 inhibitors and Kv3.1/3.2 activators with transformative potential for patients suffering from pain and cognitive disorders, respectively, which we plan to leverage for future partnerships or licensing. In addition, we expect to continue to advance our legacy oncology programs through existing and future external funding and out-licensing to capture potential value for our shareholders.

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

**Background and Rationale on Targeting Ion Channels for CNS Disorders**

***Overview of Ion Channels as a Drug Class***

Ion channels facilitate the movement of charged molecules across cellular membranes and are responsible for electrical signaling, serving as important mediators of physiological functions in the CNS. Modulation of ion channels influences neurotransmission that leads to downstream signaling in the brain. While ion channels are commonly implicated in disease, due to the complexity of ion channels and limitations in drug discovery, only a small percentage of the ion channels implicated in these diseases have drugs available to treat the disorders. Therefore, we believe that ion channels represent a significant untapped domain for future drug development across a variety of neuropsychiatric and neurological disorders.

***Hypercholinergic and Hypocholinergic Disease States***

Acetylcholine (ACh) is a neurotransmitter and neuromodulator involved in signaling in the central nervous system (CNS). ACh serves a number of critical functions, which can be impaired by diseases that influence ACh levels in the body. When levels of ACh are elevated in critical regions of the brain, the result is a "hypercholinergic disease state", whereas when levels of ACh are inadequate in critical regions of the brain, the result is a "hypocholinergic disease state" (Figure 1). Bionomics is initially seeking to treat conditions of hypercholinergic and hypocholinergic disease states using therapeutics that restore homeostasis.

*α7 Nicotinic Acetylcholine Receptor as a Target*

The α7 receptor is a member of the cys-loop, ligand-gated, ion channel superfamily, which includes several other nicotinic receptor subtypes as well as GABA-A, glycine and 5-HT3 receptors. The α7 receptor is unique because of its high calcium ion ("Ca2+") permeability and rapid desensitization. It is highly expressed in brain regions associated with cognitive performance, such as the basal forebrain, hippocampus and prefrontal cortex, as well as regions associated with emotional control, such as the amygdala and hippocampus. When the ACh neurotransmitter binds to the α7 receptor, the ion channel opens and preferentially allows calcium ions to flow into the cell. These calcium ions act as secondary messengers and trigger signaling cascades, including release of additional neurotransmitters, that contribute to the important CNS modulatory role of this receptor.

Dysfunction of the α7 receptor and altered levels of ACh have been associated with a broad array of neuropsychiatric and neurologic disorders such as SAD, GAD, PTSD, Cognitive Impairment Associated with Schizophrenia ("CIAS"), ADHD and Alzheimer's disease. Excess levels of ACh in brain regions involved in emotional control, such as the amygdala and the neocortex, can cause symptoms of anxiety and depression. While stress-induced ACh release can facilitate normal adaptive responses to environmental stimuli, known as

fight or flight, chronic elevations of ACh signaling may produce maladaptive behaviors culminating in anxiety and stressor-related disorders such as SAD, GAD and PTSD. Conversely, low levels of ACh resulting from loss of cholinergic neurons in brain regions such as the basal forebrain and hippocampus contribute to cognitive deficits in Alzheimer's disease (Figure 1).

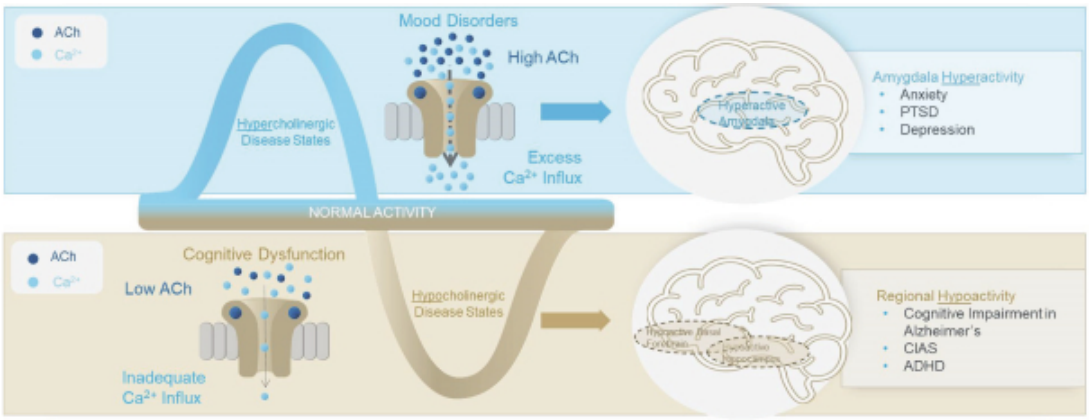



*Figure 1:CNS conditions with acetylcholine imbalance at the α7 receptor.*

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

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

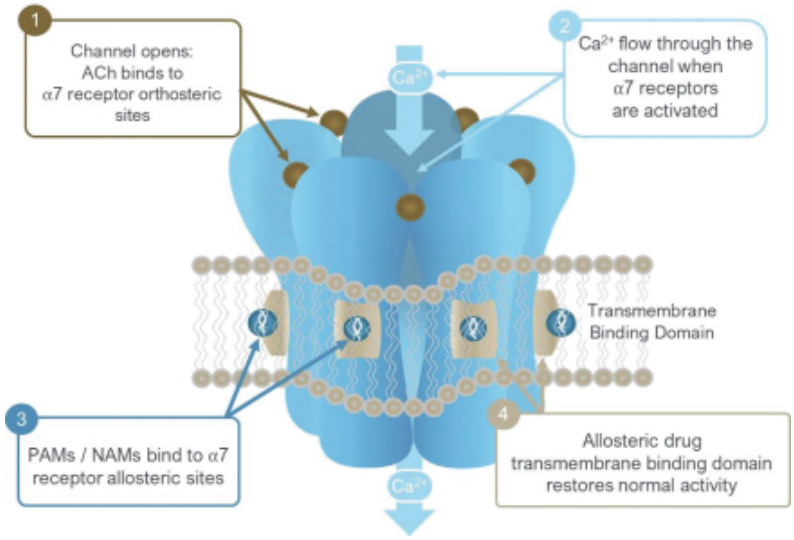



*Figure 2: Structure of the α7 receptor showing the orthosteric and allosteric binding sites.*

The α7 receptor has garnered significant attention, in particular, as a target for cognitive deficits based on receptor localization, and because of robust effects observed in preclinical studies and genetic implication of its involvement in cognitive disorders. Historically, therapeutics that modulate the α7 receptor have either targeted the orthosteric agonist sites or blocked the channel. These conventional orthosteric α7 receptor agonists have suffered from off-target activity, receptor desensitization, and a narrow therapeutic window that have limited their clinical utility. Allosteric modulators of the α7 receptor bind at the transmembrane region (see Figure 1) at sites distinct from the orthosteric sites. Allosteric modulators on their own have no effect on the receptor and act only when agonists, such as ACh, nicotine or choline, are bound to the orthosteric site. Binding to allosteric sites on the α7 receptor can diminish or enhance the effects of orthosteric agonist binding. Through the dynamic interaction between the molecules bound to each site, allosteric modulators serve to "normalize" function of the ion channel by mitigating hypercholinergic and hypocholinergic disease states (see Figure 2). As such, allosteric modulators have several potential key advantages, including potentially improved safety profiles and lower likelihood of desensitization, resulting in potentially greater efficacy, as compared to historically used orthosteric agonists or channel blockers.

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

Beyond the discovery phase, our clinical development strategy is strengthened by using an array of established and well-defined translational tools, including well-established biomarkers. We leverage biomarkers, functional magnetic resonance imaging ("MRI"), electroencephalographic activity ("EEG") and behavioral paradigms to demonstrate early proof of mechanism and biology in clinical studies in healthy volunteers and patients. In addition, we utilize robust pharmacokinetic and pharmacometric exposure-response relationship modeling in our translational and Phase 2 clinical trials to assess the target blood exposure and define the doses of the drug to be evaluated in our clinical trials, which we believe will result in an increased probability of success in the clinic.

## Our Lead Product Candidate

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

We are developing our lead product candidate, BNC210, a novel, orally administered small molecule, for the acute treatment of SAD and chronic treatment of PTSD. BNC210 is a NAM of the α7 receptor and does not exert its effect on the α7 receptor unless in the presence of an agonist, such as ACh. When BNC210 binds to the α7 receptor in the presence of ACh, it normalizes the effect of enhanced ACh signaling, thereby decreasing the flow of $Ca^{2+}$ through the channel and the subsequent downstream neurotransmitter modulation, as seen in the figure below. We believe that inhibition by BNC210 of α7 receptor dependent neurotransmission in the amygdala is key to its anti-anxiety potential. BNC210 has demonstrated clinical proof-of-concept of acute anti-anxiety activity in a prior Phase 2 clinical trial in GAD patients as well as a statistically significant reduction in panic symptoms in a clinical trial of healthy volunteers who had received cholecystokinin-4 ("CCK-4"), a peptide that induces anxiety and panic symptoms. We have initiated our Phase 2 PREVAIL trial for the acute treatment of SAD by the end of 2021 and anticipate reporting topline data by the end of 2022. We have initiated our Phase 2b ATTUNE clinical trial for the treatment of PTSD and we expect to report topline data from the trial in mid-2023.

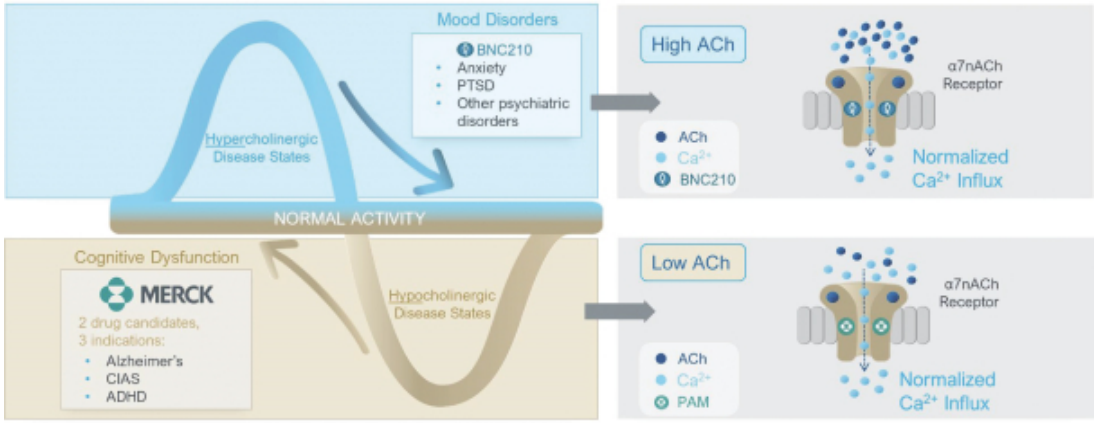



*Figure 3. Action of BNC210 depends on ACh neurotransmission and allosteric modulation of α7 receptor.*

**Disease Background and Key Disease Drivers**

***Social Anxiety Disorder***

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

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

***Post-Traumatic Stress Disorder***

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

PTSD significantly impacts all aspects of life and the day-to-day functioning of people with this debilitating disorder. In addition, PTSD severity is often worsened by co-occurring disorders that result from PTSD itself

such as major depression, substance abuse, and mood and anxiety disorders. PTSD also substantially contributes to suicide risk, further underscoring the severity and unmet need in this patient population. The Clinician-Administered PTSD Scale ("CAPS") is considered to be the gold-standard criterion measure to diagnose and assess the severity of PTSD symptoms in patients in clinical trials. CAPS is routinely updated to reflect the current DSM criteria, the latest of which is the CAPS-5. This scale measures the frequency and intensity of PTSD symptoms, which can be broadly classified into four clusters: intrusion, avoidance, negative mood and thinking, and arousal and reactivity.

Approximately 7.7 million people currently suffer from PTSD in the United States, a figure which is on the rise due to the impact of the COVID-19 pandemic that has contributed to higher rates of symptoms associated with anxiety, depression and PTSD. Approximately 8% of the U.S. population will experience PTSD within their lifetimes, making PTSD the fifth most prevalent mental health disorder in the United States. In addition, when adjusted for the frequency of traumatic event exposure, women are four times more likely to develop PTSD than men. PTSD is a complex, chronic disorder, with many symptoms and co-morbidities that make it difficult to treat.

***Current Treatments for SAD and PTSD and Their Limitations***

There remains a significant unmet medical need for over 22 million patients suffering from SAD and PTSD. Current approved pharmacological treatments include SSRIs and SNRIs, with some off-label use of benzodiazepines and beta blockers (only used for SAD). These existing treatments have multiple shortcomings, such as a slow onset of action of antidepressants, and significant side effects of these classes of drugs.

- *Antidepressants.* Antidepressants, including SSRIs and SNRIs, currently serve as first-line pharmacotherapies for SAD and PTSD. The efficacy shortcomings of these antidepressants are well-known and many patients do not achieve clinical remission, resulting in high discontinuation of therapy. For example, current estimates indicate that only 20 to 30% of PTSD patients achieve clinical remission on SSRI therapies. SSRIs/SNRIs also have tolerability issues, including gastrointestinal side effects, CNS side effects (agitation, anxiety, insomnia, dizziness and drowsiness), sexual dysfunction and sweating and also carry a black-box label warning for increased risk of suicidality in adolescents. Apart from limited or no efficacy, many patients discontinue treatment as a result of the fear of related side effects. Furthermore, SSRIs/SNRIs typically require several weeks of chronic administration before onset of efficacy, making them inadequate for the treatment of acute anxiety episodes in anxiety disorders such as SAD and as often seen in PTSD. Patients on these antidepressants often need co-administration of acute anti-anxiety medications, such as benzodiazepines.
- *Benzodiazepines*. While not FDA approved for SAD or PTSD, benzodiazepines may be prescribed off-label along with approved medications such as SSRIs/SNRIs. In addition to their distinctive sedative effects, benzodiazepines have other significant safety risks, including memory and motor impairment, serious risk of abuse, addiction, physical dependence, and withdrawal reactions, as highlighted in the FDA's Drug Safety Communication in September 2020. Furthermore, emerging evidence indicates that benzodiazepines may inhibit brain areas involved in fear learning, including the amygdala, further delaying recovery and counteracting the effects of the treatment.
- *Beta Blockers*. Beta blockers are a class of blood pressure lowering medications that are commonly used off-label for patients with SAD to help reduce some of the physical symptoms of anxiety, such as an increased heart rate, sweating, or tremors. However, these therapies have not been effective in reducing overall anxiety.

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

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

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

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

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

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

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

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

*Clinical Development of BNC210*

To date, we have studied BNC210 in approximately 400 subjects across 12 completed clinical trials, including in healthy volunteers, elderly patients suffering from agitation and patients with GAD and PTSD. BNC210 has not demonstrated the severe side effects commonly associated with SSRIs/SNRIs and benzodiazepines. We believe that the tolerability data that we have observed to date supports both acute and chronic dosing.

In addition, BNC210 has demonstrated clinical proof-of-concept of acute anti-anxiety activity in a prior Phase 2 clinical trial in GAD patients as well as a statistically significant reduction in panic symptoms in a CCK-4 induced panic attack clinical trial of healthy volunteers. The table below summarizes our clinical trials for BNC210.

*Summary of BNC210 Clinical Trials*

| Phase | Description | Participants / Setting | Subjects Enrolled / Administered BNC210* | BNC210 Formulation and Doses | Location |
|---|---|---|---|---|---|
| 1 | Single Ascending Dose Safety and PK | Healthy volunteers / In-clinic | 32/24 | Suspension; single doses (5 to 2000 mg) | Australia |
| 1 | Single Ascending Dose Safety and PK; Food Effect | Healthy volunteers / In-clinic | 4/3 | Suspension; single doses (300 to 2000 mg) | Australia |

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

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

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

There have been no apparent BNC210 dose-related trends in the type or severity of adverse events reported, or dose-related trends in the laboratory safety data, vital signs, physical examinations or electrocardiogram ("ECG") measurements. Across all 12 completed clinical trials, including a 12-week Phase 2 PTSD trial, the most commonly reported adverse events were headache (18%), somnolence (6%) and nausea (5%). The majority of these adverse events were graded as mild. There have been two serious adverse events ("SAEs") that were deemed by the investigators to be at least possibly related to BNC210: one SAE reported for hypotension (with alternative causality of dehydration) for an elderly patient was deemed possibly related to study drug by the independent investigator, however, after a saline infusion, blood pressure returned to within normal limits within 45 minutes and the subject continued on the study; and one SAE for elevated liver function tests reported 14 days after last treatment dose for a PTSD subject who remained asymptomatic throughout the study and in follow up was deemed probably related to study drug by the independent investigator. For the SAE related to elevated liver function, it was subsequently noted in a safety report to the FDA that the Independent Safety Monitoring Board for the RESTORE study did not believe that this adverse event met the criterion for an SAE. In addition, we evaluated the abuse potential of BNC210 in three healthy volunteer studies at doses up to 2000 mg per day for eight days using the Addiction Research Center Inventory 49 item questionnaire ("ARCI49"), which showed no significant effects in addiction potential across the five abuse-potential categories evaluated.

***Phase 1 Safety, Tolerability and Pharmacokinetic Clinical Trials in Healthy Subjects Using a Liquid Suspension Formulation***

We conducted two Phase 1 clinical trials with BNC210 in 36 healthy subjects to examine the safety and pharmacokinetics of our product candidate using a liquid suspension formulation. Subjects in the double-blind, placebo-controlled trials were administered a single dose of BNC210 ranging from 5 to 2000 mg in the presence and absence of food. BNC210 was observed to be generally well tolerated with no clinically significant findings observed in vital signs, ECG, clinical chemistry, hematology or urinalysis. The pharmacokinetic analysis indicated that BNC210 drug levels were substantially higher in subjects when taken with food.

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

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

We conducted a Phase 1 clinical trial to demonstrate BNC210 target engagement at brain nicotinic receptors measured by EEG activity (see figure below). On Day -1, one day prior to administration of BNC210, 24 healthy volunteers were administered oral doses of nicotine ranging from 0.5 to 2.0 mg. We then measured the change in the power in the α2 EEG band, a measure of nicotine response in the brain. We observed a dose-dependent increase in power in the α2 EEG band following nicotine administration, which we believe is primarily attributable to the activation of two key nicotinic receptors: α4ß2 and α7. Subjects were then dosed orally with the 2000 mg BNC210 liquid suspension with food for seven days and were re-challenged on Day 7 with the same doses of nicotine used on Day -1. BNC210 demonstrated a statistically significant reduction in the power in the α2 EEG band following nicotine administration, which we believe demonstrates target engagement and negative modulation of the α7 receptor. A result is considered to be statistically significant when the probability of the result occurring by random chance, rather than from the efficacy of the treatment, is sufficiently low. The conventional method for determining the statistical significance of a result is known as the "p-value," which represents the probability that random chance caused the result (e.g., a p-value of 0.01 means there is a 1% probability that the difference between the control group and the treatment group is purely due to random chance). Generally, a p-value of less than 0.05 is considered statistically significant. We believe the residual nicotine-induced EEG responses of subjects treated with BNC210 is primarily attributable to the activation of the α4ß2 nicotinic receptor, which BNC210 is not designed to engage.

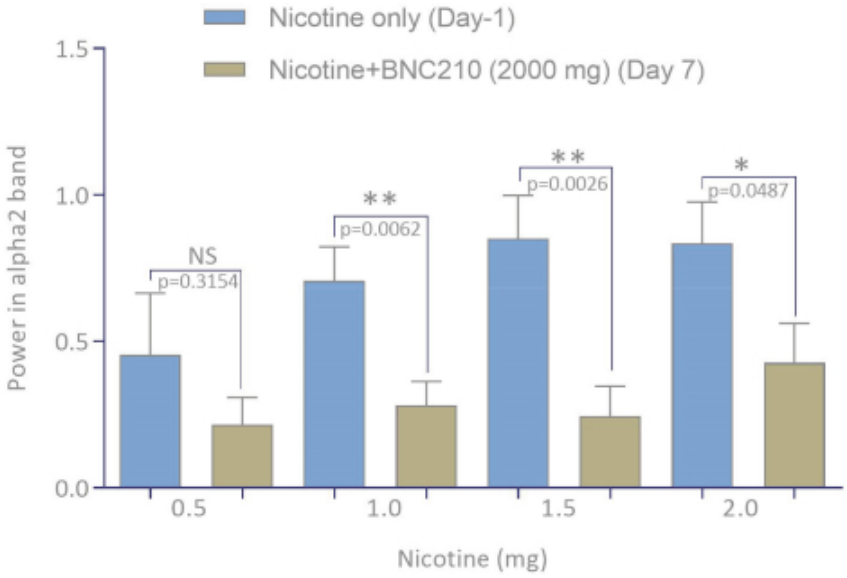



*Figure 4: Demonstration of BNC210 brain penetration and target engagement of α7 receptor in humans.*

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

We conducted a randomized, placebo-controlled, double-blind Phase 1 clinical trial in 60 healthy subjects to evaluate the anti-anxiety effects of BNC210. These subjects were administered CCK-4, a peptide that induces anxiety and panic symptoms. CCK-4 induced panic symptoms in 15 subjects, or approximately 25% of the subjects, which is consistent with the CCK-4 induced panic attack rate in other trials. Subjects in a supervised in-clinic setting received a single dose of 2000 mg of BNC210 liquid suspension formulation with food seven hours prior to the CCK-4 challenge. BNC210 met its primary endpoint, demonstrating statistically significant reduction in both the number and intensity of panic symptoms on the Panic Symptoms Scale ("PSS") compared to placebo 10 minutes after the CCK-4 injection, as seen in the figure below (p=0.048 and p=0.041, respectively). This clinical trial also demonstrated that the emotional stability of BNC210-treated subjects returned to baseline within 10 minutes compared to 60 minutes for placebo treated subjects. These findings were consistent with our prior preclinical studies in rodents where BNC210 overcame the effects of a CCK-4 challenge and enhanced fear extinction, as well as demonstrated similar activity to benzodiazepines without the narrow dose response common to that class of drugs.

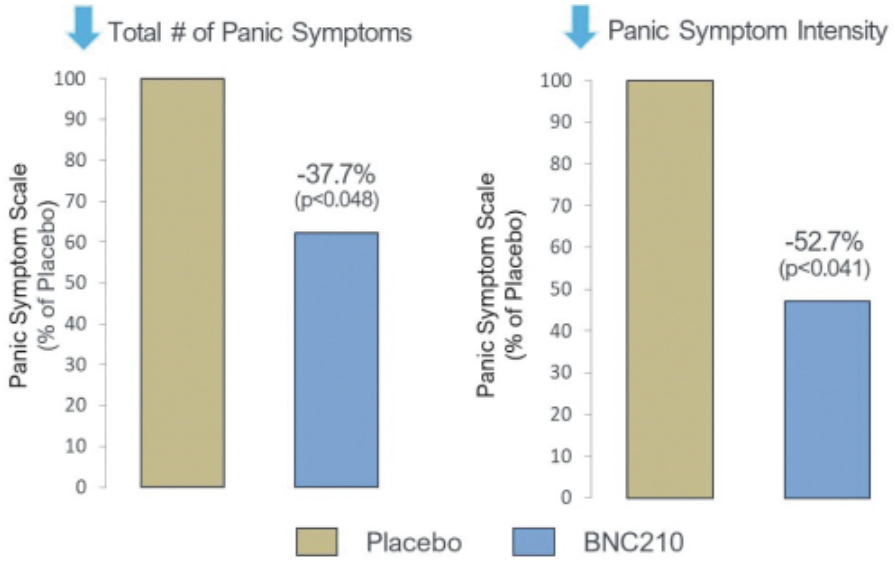


*Figure 5: Results from BNC210 in a human CCK-4 challenge panic disorder.*We also conducted a Phase 2a randomized, double-blind, placebo-controlled, four-way crossover clinical trial in 24 newly diagnosed, treatment-naive GAD patients in the in-clinic setting evaluating the neural imaging response of patients exposed to “fearful faces” and their behavioral response to threat avoidance. Each subject was treated in a randomized manner with a single dose of 300 mg BNC210, 2000 mg BNC210, 1.5 mg lorazepam or placebo with a washout period of at least five days. The primary endpoints were changes in cerebral perfusion using functional MRI in the resting state and changes in activation of the region of the brain responsible for emotional control, the amygdala, during the performance of an emotional task. Secondary endpoints were changes in defensive behavior (Flight Intensity) using the Joystick Operated Runway Task (“JORT”) and changes in affective self-report, which are measures of anxiety. BNC210 300 mg, similarly to lorazepam, statistically significantly reduced amygdala reactivity to “fearful faces” relative to placebo (BNC210 300 mg left amygdala p=0.011; BNC210 300 mg right amygdala p=0.006; lorazepam right amygdala p=0.047) (Figure 6). 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 7). Furthermore, in this head-to-head study, BNC210 300 mg and 2000 mg statistically significantly reduced the intensity of defensive behavior compared to placebo, while lorazepam did not (BNC210 300 mg p=0.007; BNC210 2000 mg p=0.033) (Figure 8). In addition, the 300 mg dose of BNC210 significantly reduced self-reported anxiety (p=0.003).

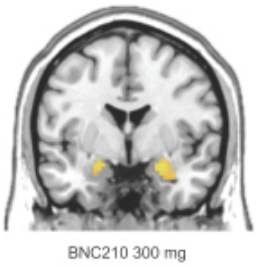



*Figure 6: BNC210 300 mg significantly reduced activation of left and right amygdala while viewing fearful faces compared to placebo (L: p=0.011; R: p=0.006).*

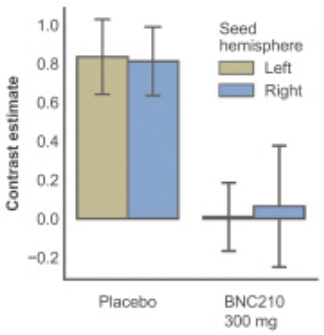



*Figure 7: BNC210 300 mg significantly reduced connectivity between the amygdala and ACC while viewing fearful faces compared to placebo (p=0.012).*

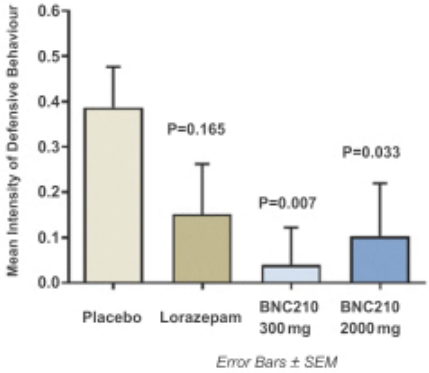



*Figure 8: BNC210 significantly reduced threat avoidance behavior of anxious subjects in the JORT behavioral task compared to placebo.*

***Phase 2 RESTORE PTSD Clinical Trial Using Liquid Suspension Formulation: Summary, Pharmacokinetic Modeling and Pharmacometric Analysis***

Our RESTORE trial was a randomized, double-blind, placebo-controlled Phase 2 clinical trial in the outpatient setting that enrolled 193 adult patients diagnosed with PTSD across 20 sites in the United States and six sites in Australia. There were four treatment groups, including a placebo arm and three BNC210 dose arms (150 mg, 300 mg, 600 mg) of the liquid suspension formulation given twice daily with food. The primary endpoint of this study was a decrease in PTSD symptom severity between placebo and BNC210 treatment groups as measured by the CAPS-5 at 12 weeks, a validated clinical endpoint. Secondary endpoints included measurement of effects on components of the CAPS-5 PTSD symptom clusters, measures of anxiety and depression, well-being, sleep, and safety. While the trial did not meet the primary endpoint, we observed evidence of anti-depressant effects and trends for anti-anxiety activity in the CAPS-5 symptom clusters in the study primarily in the high dose BNC210 600 mg group (CAPS-5 Criterion D Negative Alterations in Cognitions and Mood at Week 1 p=0.037). Furthermore, the overall safety analysis showed adverse event reporting and other safety parameters such as laboratory analyses, vital signs, physical examinations, and ECG were similar for placebo and each of the three BNC210 treatment groups, indicating that BNC210 was well tolerated in this patient population over the 12-week dosing period. Subsequently, we performed extensive population pharmacokinetic modeling and pharmacometric analysis on the RESTORE trial. Population pharmacokinetics indicated that the plasma exposure achieved in the patients in the RESTORE trial, which was an outpatient trial, was substantially (approximately 50%) less than projected from the in-clinic multiple ascending dose ("MAD") pharmacokinetic study in healthy volunteers.

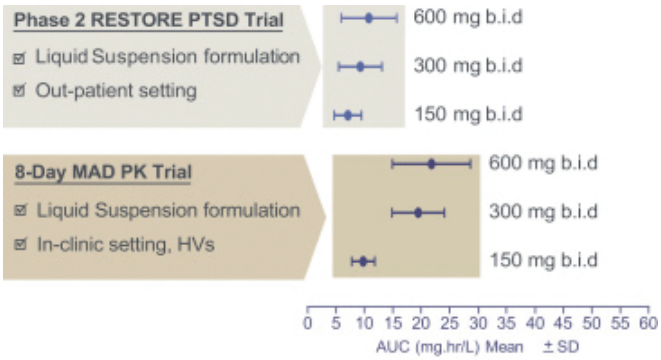



*Figure 9: Out-patient Phase 2 PTSD RESTORE trial did not achieve exposure projected from in-clinic MAD study in healthy volunteers.*

Furthermore, a pharmacometric blood exposure-response relationship was modeled which showed potential for BNC210 to have clinical benefit in PTSD provided that adequate exposures of 25 mg.hr/L and above are achieved ($p<0.01$), as seen in the figure below. These data were shared with the FDA at a meeting and provided guidance for the Phase 2b ATTUNE PTSD clinical trial.

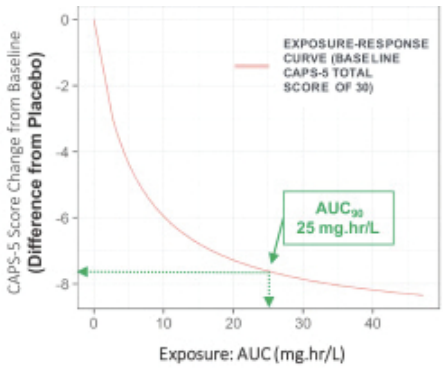



*Figure 10: Pharmacometric model predicted BNC210 effect in a PTSD patient with a baseline CAPS-5 score of 30.*

***Novel, Proprietary Tablet Reformulation Effort***

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

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

**Liquid Suspension Formulation** **Tablet Formulation**

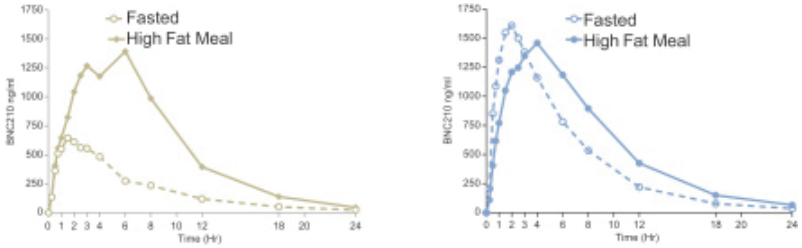



*Figure 11: New tablet formulation overcomes food effect in healthy subjects.*

We carried out a second Phase 1 single ascending dose pharmacokinetic clinical trial in five healthy subjects in which each subject, in a fasted state, was dosed with 600 mg, 900 mg, and 1200 mg of BNC210 tablet formulation with a wash-out period of at least five days between treatments. For comparison, the results of the 300 mg dose in fasted subjects from a previous study using the tablet formulation is included in the dataset. The plasma concentrations and exposures measured in fasted healthy volunteers increased in a dose proportional manner, demonstrating improved dose linearity with the tablet formulation compared to the liquid suspension. The BNC210 tablet formulation had a rapid absorption profile reaching maximal concentrations in the blood between 45 to 105 minutes, potentially making it a well-suited formulation for treatment of acute anxiety in SAD patients in the ongoing Phase 2 PREVAIL trial. BNC210 was observed in this study to be well tolerated at all dose levels tested.

We also carried out a multi-dose seven-day dosing pharmacokinetic study in ten healthy volunteers (five females and five males) to evaluate the dosing regimen (900 mg given twice daily) proposed for the Phase 2b ATTUNE PTSD clinical trial. The tablet formulation of BNC210 given at 900 mg twice daily had 12-hourly exposure levels ranging from 33-57 mg.h/L, which exceed the 12-hourly blood exposure of approximately 25 mg.h/L, which our pharmacometric analysis predicted as necessary to meet the primary endpoints for effectiveness for treating PTSD patients in future clinical trials. Furthermore, the results showed that with twice daily dosing there was no gender-based difference in exposure and that BNC210 continued to be well-tolerated, even at the higher exposure levels achieved after seven days of dosing in the healthy volunteers.

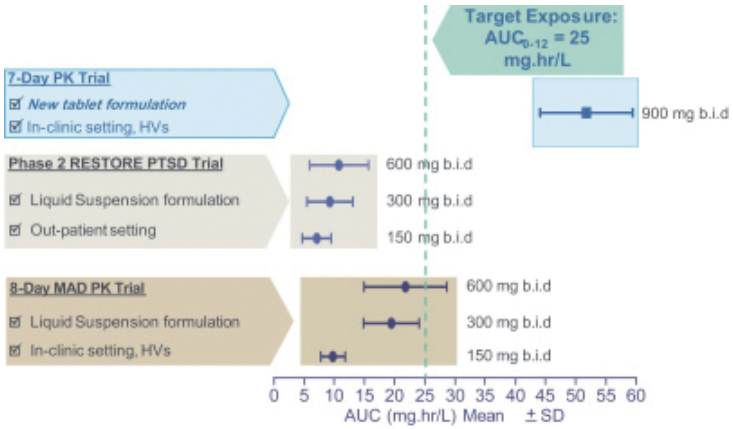



*Figure 12: Pharmacokinetic (PK) study of tablet formulation in healthy volunteers achieved target exposure.*

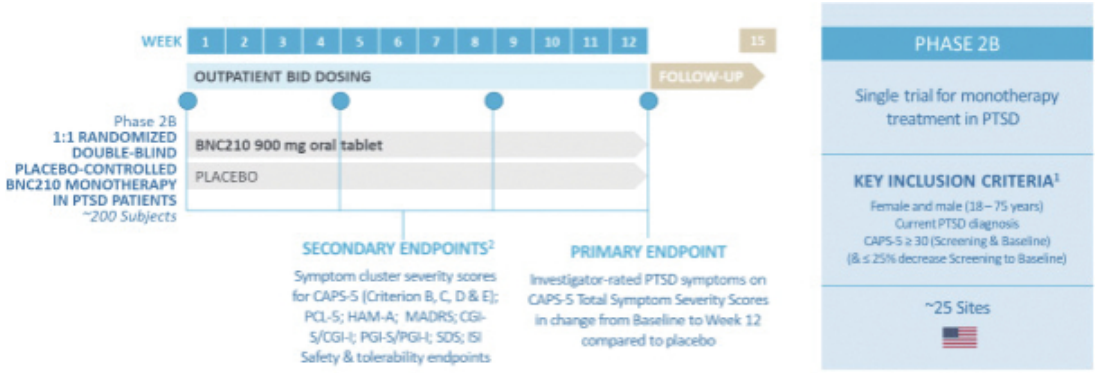
***BNC210 Clinical Development in SAD***

We have initiated an SAD trial, which we refer to as the PREVAIL Study, evaluating the effects of acute dosing of BNC210 on performance anxiety, using a standardized public speaking challenge. We are building on the favorable attributes of our novel tablet formulation with a rapid absorption profile reaching maximal concentrations in the blood between 45 to 105 minutes, providing the potential for on demand use to treat symptoms of social anxiety which result from often predictable anxiety-provoking stressors. Furthermore, FDA's prior support of using a public speaking challenge and the SUDS as a Phase 3 registrational endpoint for approval makes SAD an attractive, potentially more rapid path-to-market indication to further explore in clinical development.

In October 2021, we received IND clearance from the FDA to evaluate BNC210 for the acute treatment of SAD and have inititatedour Phase 2 PREVAIL trial of BNC210 for the acute treatment of SADtargeting the large unmet medical need for this patient population. The PREVAIL Study is a randomized, double-blind, parallel three-arm (placebo, 225 mg BNC210 or 675 mg BNC210) multi-center Phase 2 clinical trial which will compare the tablet formulation of BNC210 to placebo on anxiety levels in patients with SAD during an anxiety-provoking behavioral task such as being asked to speak on a topic. Participants will be orally administered a single dose of study treatment approximately one hour prior to the behavioral task. The primary endpoint of the PREVAIL Study is to compare BNC210 to placebo on self-reported anxiety levels using the SUDS during the behavioral task. Secondary endpoints include other scales measuring participants' anxiety levels, in anticipation of, and during the behavioral task, as well as an evaluation of the safety and tolerability of BNC210 in this population. The PREVAIL Study is being conducted at approximately 15 sites in the U.S. and will enroll approximately 150 adult patients suffering with SAD. The study participants must score at least 70 on the Liebowitz Social Anxiety Scale (i.e., marked to severe social anxiety), which is a scale that assesses a patient's reported level of social phobia in a range of social interactions and performance situations during the past week. We expect to report topline data by the end of 2022.

***BNC210 Clinical Development in PTSD***

We have an ongoing Phase 2b clinical trial, which we refer to as the ATTUNE trial, evaluating BNC210 monotherapy treatment in approximately 200 PTSD patients and we expect results in mid-2023. The ongoing trial is a one-to-one randomized, double-blind, placebo-controlled, parallel two-arm (placebo or BNC210 900 mg twice daily) 12-week treatment study that will assess the efficacy and safety of our newly developed tablet formulation of BNC210. The primary efficacy endpoint of this trial is the effect of BNC210 compared to placebo on baseline to endpoint change in CAPS-5 total symptom severity scores after 12 weeks of treatment. In addition, several investigator and self-reported secondary efficacy endpoints related to CAPS-5 symptom cluster severity scores and anxiety and depression measures along with safety and tolerability endpoints will be reported.




1. *Eligibility Criteria = CAPS-5 Total Symptom Severity Score ≥ 30 at Screening and Baseline (and ≤ 25% decrease in score from Screening to Baseline)*
2. *BID = Twice daily dosing; CAPS-5 = Clinician-Administered PTSD Scale for the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5); PCL-5 = PTSD Checklist for DSM-5; HAM-A = Hamilton Anxiety Rating Scale; MADRS = Montgomery-Asberg Depression Rating Scale; CGI = Clinical Global Impressions; PGI = Patient Global Impressions; SDS = Sheehan Disability Scale; ISI = Insomnia Severity Index*

*Figure 13: Phase 2b ATTUNE clinical trial design.*

We also have a memorandum of understanding with EmpathBio to explore the feasibility of combination treatment of an MDMA derivative EMP-01 and BNC210 which could have the potential to further expand the market for BNC210 for the treatment of PTSD. Depending on the results of the preclinical feasibility studies, we intend to enter into a definitive agreement with EmpathBio, but there is no assurance we will do so. We intend to determine the feasibility of behavioral therapy with MDMA/EMP-01 followed by treatment with BNC210 which may have the potential to reduce the intensive in-clinic treatment sessions that are currently used with MDMA treatment. Under the proposed collaboration, it is anticipated that EmpathBio would be primarily responsible for such trials and we would be responsible for supplying any and all amounts of BNC210 required for such trials. We and EmpathBio have agreed to reasonably update each other of significant events relevant to intended timing of preclinical and clinical studies related to the proposed collaboration. Under the proposed collaboration, we and EmpathBio would each retain all rights in relation to our or their own intellectual property, respectively. Ownership of any intellectual property resulting from the proposed collaboration is expected to be determined in accordance with U.S. patent law, unless otherwise agreed to by us and EmpathBio; provided that EmpathBio would own any intellectual property specific to EMP-01 and/or which employs or is derived from EmpathBio's intellectual property and, subject to the foregoing, we would own any intellectual property specific to BNC210 and/or which employs or is derived from our intellectual property.

***Future Indication Expansion Opportunities for BNC210***

We believe BNC210 has broad potential across acute and chronic anxiety and stressor-related disorders with high unmet medical need. Our clinical, regulatory and commercial strategy is to initially develop BNC210 in an acute indication with a high unmet medical need for which there is no FDA-approved treatment, such as SAD and a chronic indication with a high unmet medical need, such as PTSD, for which there are limited treatment options. Assessment of BNC210 in these two distinct settings of anxiety and stressor-related disorders will also allow us to define the dosing paradigm which may be applicable to other indications across both acute and chronic settings. BNC210 has already demonstrated the potential for acute treatment of GAD patients in a Phase 2 clinical trial and would represent a logical treatment paradigm for the chronic treatment of this indication along with chronic treatment of SAD, and adjustment disorders with anxiety. Our clinical and regulatory strategy would be similar to that used for the oral calcitonin gene-related peptide ("cGRP") antagonists for the treatment of migraine in which the first indications seeking approval were for the acute treatment of a migraine episode followed by chronic treatment for a decrease in the monthly migraine episodes.

**Other Pipeline Programs**

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

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

To overcome the challenges with orthosteric agonists, we embarked on an α7 PAM discovery program which led to the identification of BNC375, a novel α7 PAM which is selective over related receptors and potentiates ACh-evoked α7 currents with no observed effect on receptor desensitization kinetics. In June 2014, we entered into a strategic collaboration with Merck to develop novel PAMs, including our BNC375 research program, for the treatment of cognitive dysfunction associated with Alzheimer's disease and other central nervous system conditions. Under the collaboration, BNC375 was further characterized showing that it enhanced long-term potentiation of electrically evoked synaptic responses in rat hippocampal slices and *in vivo*, which is an established preclinical surrogate for memory enhancement. Systemic administration of BNC375 reversed scopolamine-induced cognitive deficits in rat novel object recognition and rhesus monkey object retrieval detour ("ORD") tasks over a wide range of exposures, showing no evidence of an inverted U-shaped dose-effect curve. The compound also improved performance in the ORD task in aged African green monkeys. African green monkeys display pathological hallmarks of Alzheimer's disease such as amyloid plaques and constitute a valuable translational model to assist in the development of drug candidates for Alzheimer's disease. Moreover, *ex vivo* 13C-NMR analysis indicated that BNC375 treatment enhanced neurotransmitter release in rat medial prefrontal cortex. These findings suggest that α7 receptor PAMs may have multiple advantages over orthosteric α7 receptor agonists for the treatment of cognitive dysfunction associated with CNS diseases.

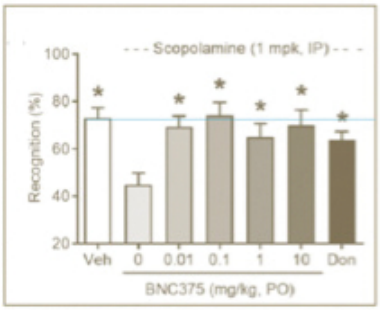



*Figure 14: BNC375 in the Rat Novel Object Recognition memory test. Scopolamine is used to impair memory which is represented below the dotted Scopolamine line. Donepezil ("Don") (Aricept), a marketed drug for the treatment of cognitive impairment, is used as the positive control. BNC210 treatment was effective over a broad dosing range (1000-fold) and out-performed Donepezil by reversing the memory impairment back to the level of control animals (blue line). Veh = 30% Captisol in water; * = p<0.05.*

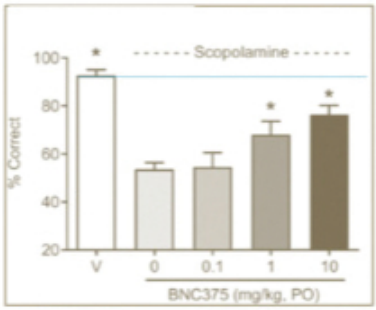



*Figure 15: BNC375 in the Rhesus Object Retrieval Detour (ORD) memory test. Scopolamine was used to impair memory which is represented below the dotted Scopolamine line. BNC375 dose dependently reversed this impairment back towards the level of the control animals (blue line). V = 30% Captisol in water; * = p<0.05.*

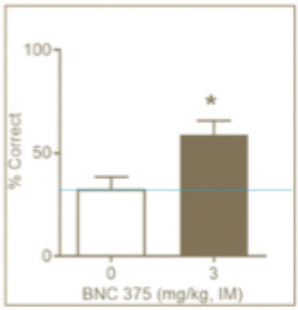



*Figure 16: BNC375 statistically significantly reversed memory impairment (blue line) in African green monkeys in the ORD model. * = p<0.05.*

Our collaboration with Merck currently includes two candidates which are PAMs of the α7 receptor that are in early-stage Phase 1 safety and biomarker clinical trials for treating cognitive impairment. The first compound has completed Phase 1 safety clinical trials in healthy subjects and there are ongoing biomarker studies. In 2020 a second molecule that showed an improved potency profile in preclinical animal models was advanced by Merck into Phase 1 clinical trials.

***Emerging CNS Programs***

We have an emerging CNS pipeline with two small molecule programs targeting ion channels at a similar stage of discovery to when we entered into the 2014 Merck License Agreement with Merck that may be available for future partnering.

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

Voltage gated sodium channels ("Navs") are responsible for the generation and conduction of action potentials in peripheral pain pathways. Gain and loss of function mutations in selective sodium channel subtypes, Nav1.7 and Nav1.8, are associated with human pain syndromes where extreme pain or no pain respectively, is experienced. We have patented two series of small molecule inhibitors with functional selectivity for Nav1.7 and Nav1.8 voltage gated sodium channels for the treatment of chronic pain without the potential for addiction and sedation associated with opioid treatments and pregabalin, respectively. Representative molecules from each series have been observed to reverse pain in the formalin paw model in mice.

***Legacy Oncology Programs***

We have a portfolio of legacy clinical-stage oncology programs targeting cancer stem cells (BNC101) and tumor vasculature (BNC105) that we have progressed through external funding for clinical trials and out-licensing to capture future value for our shareholders. Cancer stem cells are the seeds that give rise to initial tumor formation and if left unchecked, give rise to tumor recurrence and metastasis. Our first legacy oncology program is BNC101, a novel humanized monoclonal antibody that targets LGR5, a cancer stem cell receptor highly overexpressed in most solid tumors, including colorectal, breast, pancreatic, ovarian, lung, liver and skin cancers. In preclinical studies, BNC101 was associated with a reduction in the frequency of cancer stem cells derived from primary patient colorectal tumors both *in vitro* and *in vivo*. BNC101 has completed a Phase 1 clinical trial in patients with colorectal cancer and shown target engagement. In preclinical studies, BNC101 has shown good potential for the treatment of gastrointestinal tumors in combination with an antibody drug conjugate or CAR-T therapy. In November 2020, we exclusively licensed BNC101 to Carina Biotech for the development of CAR-T therapeutics, which is currently in preclinical development, in return for milestones and royalties or a percentage of the out-licensed revenues. In September 2021, Carina Biotech announced that it plans to initiate a clinical trial of BNC101 for the treatment of advanced colorectal (bowel) cancer in late 2022. See “Business—IP License Agreement with Carina Biotech.” Our second legacy oncology program, BNC105, is a novel vascular tubulin polymerization inhibitor agent for treatment of cancer, which disrupts the blood vessels that nourish tumors. BNC105 has been evaluated in six prior clinical trials. We plan to advance these oncology programs only through existing and potentially new partnerships.

**Competition**

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

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

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

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

Our competitors fall primarily into the following categories:

- **SAD:** There are currently no FDA-approved drugs for the acute treatment of SAD. There are four FDA-approved generic antidepressants for treatment of SAD that include paroxetine (Paxil), previously marketed by GlaxoSmithKline, sertraline (Zoloft) and venlafaxine (Effexor), both previously marketed

by Pfizer, and fluvoxamine (Luvox), marketed by Jazz Pharmaceuticals. Although not FDA-approved for the acute treatment of SAD, generic benzodiazepines and beta blockers are used off-label use as well. Additionally, we are aware of several product candidates in clinical development that are being developed for the acute treatment of SAD, by VistaGen Therapeutics and Vanda Pharmaceuticals, among others.

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

**Manufacturing**

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacturing of our product candidates for preclinical and clinical testing, as well as for commercial manufacturing if our product candidates receive marketing approval. We use additional contract manufacturers to fill, label, package, store and distribute our investigational drug products and currently expect to continue to do so for commercial supplies of our product candidates, if approved. It is our intent to identify and qualify additional manufacturers to provide active pharmaceutical ingredient and formulate drug product, as well as fill-and-finish services prior to submission of an NDA to the FDA for any product candidates that complete clinical development.

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

**Commercialization**

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

**Research Collaboration and License Agreement with Merck**

In June 2014, we entered into a research collaboration and license agreement (as amended, the “2014 Merck License Agreement”) with Merck Sharp & Dohme Corp., a wholly owned subsidiary of Merck & Co., Inc., Kenilworth NJ, USA (“Merck”) to develop compounds targeting cognitive dysfunction associated with Alzheimer’s disease and other central nervous system conditions. Pursuant to the 2014 Merck License Agreement, we granted Merck (i) an exclusive (even as to us and our affiliates), worldwide, sublicensable license under certain of our patent rights and know-how to research, develop, make, have made, use, offer to sell, sell, import and/or otherwise exploit certain α7 activator compounds and products containing such compounds for

any and all uses in humans and animals, including any prophylactic, therapeutic and/or diagnostic uses, subject to certain of our retained rights and (ii) an exclusive (even as to us and our affiliates), worldwide, sublicensable, perpetual, irrevocable, fully-paid license under certain of our patent rights and know-how to research, develop, make, have made, use, offer to sell, sell, import and/or otherwise exploit certain α7 PET ligands and products containing such ligands for any and all uses in humans and animals, including any prophylactic, therapeutic and/or diagnostic uses. Additionally, in the event that the research, development, making, having made, use, offer for sale, sale, import and/or other exploitation by Merck of the licensed compounds and licensed products would infringe, during the term of the 2014 Merck License Agreement, any of our additional patent rights owned or controlled by us that is not part of the foregoing licenses granted, we granted Merck a non-exclusive, worldwide, sublicensable, royalty-free license under such additional patent rights to research, develop, make, have made, use, offer for sale, sale, import and/or otherwise exploit such licensed compounds and licensed products. Furthermore, we granted Merck a covenant not to sue or otherwise enforce any patent rights, know-how, or other intellectual property rights related to the α7 activator compounds and products.

We are subject to limited information rights under the 2014 Merck License Agreement. As such, we are dependent on Merck to provide us with any updates related to clinical trial results, serious adverse events and ongoing communications with FDA 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.

Under the 2014 Merck License Agreement, Merck funded certain research and development activities on an FTE basis pursuant to a research plan. Merck funds all ongoing and future research and development activities, including clinical development, and worldwide commercialization of any products development from the collaboration. We received upfront payments totaling $20 million, which included funding for FTEs for the first twelve months, and another $10 million in February 2017 when the first compound from the collaboration initiated Phase 1 clinical trials and we are eligible to receive up to an additional $465 million in milestone payments for achievement of certain development, regulatory and commercial milestones. Further, Merck is obligated to pay us tiered royalties in the mid single digit to low sub-teen double digit percentage range on annual net sales of the licensed products, subject to customary royalty reductions upon certain events. Merck's royalty obligations will continue on a licensed product-by-licensed product and country-by-country basis until the later of (i) the last-to-expire valid patent claim claiming the applicable licensed compound contained in such licensed product as a composition of matter in such country or (ii) 10 years after the first commercial sale of such licensed product in such country.

The 2014 Merck License Agreement will expire upon the expiration, if not otherwise terminated earlier pursuant to the terms thereof, of all royalty obligations of Merck, and upon such expiration, licenses granted to Merck with respect to the licensed compounds and licensed products will become fully paid-up, irrevocable, perpetual licenses. Merck has the right to terminate the 2014 Merck License Agreement for convenience upon advance written notice to us. Further, Merck may terminate the 2014 Merck License Agreement with immediate effect if we undergo change of control. Additionally, either party may terminate the Merck Agreement for (i) the other party's material breach that is not remedied within the specified time period and (ii) the other party's bankruptcy or other insolvency events. If Merck terminates the 2014 Merck License Agreement because of our uncured material breach or bankruptcy (or other insolvency events), licenses granted to Merck with respect to the licensed compounds and licensed products will become fully paid-up, irrevocable, perpetual licenses.

**IP License Agreement with Carina Biotech**

In November 2020, we entered into an IP license agreement (the "Carina Biotech License") with Carina Biotech. Pursuant to the Carina Biotech License, we granted Carina Biotech 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 Biotech is obligated to use commercially reasonable efforts to commercially develop and exploit licensed products in each country in which Carina Biotech obtains regulatory approval for the licensed products. Carina Biotech is responsible for conducting all regulatory activities for the licensed products. We are obligated to assist Carina Biotech as reasonably requested from time to time in connection with its regulatory filings. We are also obligated to provide technology transfer to Carina Biotech, at Carina Biotech's request, of know-how and technical information that is useful or necessary for Carina Biotech to fully exercise the rights licensed to it under the agreement.

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

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

**Research and License Agreement with Ironwood Pharmaceuticals**

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

**Intellectual Property**

*Central Nervous System*

As of September 5, 2022, we owned over 15 issued U.S. patents, two pending U.S. patent applications, two pending Patent Cooperation Treaty ("PCT") applications, over 65 granted foreign patents, and over 15 pending foreign patent applications in our central nervous system intellectual property portfolio.

In regards to our BNC210 product candidate, we own:

- one patent family which includes eight issued U.S. patents and 15 foreign patents granted in Australia, Canada, France, Germany, the United Kingdom, and Japan, with claims directed to the composition of matter of BNC210, methods of preparing BNC210, and methods of treating anxiety and depressive disorders using BNC210, which are expected to expire in October, 2027, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable;

- one patent family which includes one issued U.S. patent and six foreign patents granted in Australia, Canada, the United Kingdom, Germany, and Japan, with claims directed to the manufacture and method of preparing BNC210, which are expected to expire in May, 2032, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable;
- one patent family which includes one issued U.S. patent and eight foreign patents granted in Australia, Canada, the United Kingdom, Germany, France, Mexico, New Zealand and Hong Kong, with claims directed to the crystalline form of BNC210, which are expected to expire in May, 2033, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable; and
- one patent family which includes a pending PCT application, WO 2021056048, with claims directed to solid form formulations of BNC210 and have submitted national phase filings in the United States, Canada, China, Europe, Japan, Korea, Mexico, New Zealand, Israel, and Australia. The patent applications claiming priority to this PCT application, if issued, are expected to expire in February, 2040, 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 September 5, 2022, we owned over 15 issued U.S. patents, over five pending U.S. patent applications, three pending PCT applications, over 35 granted foreign patents, and over 50 pending foreign patent applications in our oncology intellectual property portfolio.

In regards to our BNC101 product candidate, we own:

- one patent family which includes one granted U.S. patent and 4 foreign patents granted in Australia, France, Germany, and United Kingdom, with claims directed to the methods of blocking cancer stem cell growth using BNC101, which are expected to expire in October 2033, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable;
- one patent family which includes two issued U.S. patents and two foreign patents granted in Australia, with claims directed to the methods of treating cancer using BNC101, which are expected to expire in October 2033, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable;
- one patent family which includes two issued U.S. patents and eight foreign patents granted in Australia, Japan, China, France, Germany, United Kingdom, New Zealand, and Hong Kong with claims disclosing the humanized anti-LGR5 antibodies for the treatment of cancer, which are expected to expire in October 2035, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable; and
- one patent family which includes one issued U.S. patent with claims disclosed the method of administration of an anti-LGR5 monoclonal antibody to treat certain cancers, which are expected to expire in March 2037, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable.

In regards to our BNC105 product candidate, we own:

- one patent family which includes five granted U.S. patents and seven foreign patents granted in Australia, Canada, France, Germany, the United Kingdom, Japan, and New Zealand, with claims directed to the composition of matter of BNC105 and methods of treatment cancer using BNC105,

which are expected to expire in February, 2027, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable;

- one patent family which includes one issued U.S. patent and seven foreign patents granted in Australia, Canada, Hong Kong, China, France, German, and the United Kingdom, with claims directed to the manufacture of BNC105, which are expected to expire in July, 2031, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable;
- one patent family which includes one issued U.S. patent, one foreign patent granted in China, and 5 foreign patent applications pending in Australia, Canada, Europe, New Zealand, and Hong Kong, with claims directed to the combination of BNC105 and ibrutinib in CLL, where the granted patents and the patent applications, if issued, are expected to expire in March, 2036, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable; and
- one patent family which includes one pending U.S. patent application and 3 foreign patent applications pending in Australia, China and Europe, with claims directed to using BNC105 in the treatment of acute myeloid leukemia, where the patent applications, if issued, are expected to expire in October, 2038, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable.

In addition to the above described patent families, we have two pending PCT applications, WO 2019218025 and WO 2019218024, with claims directed to modulators of ion channels and their uses in treating chronic pain, and have submitted national phase filings in the United States (a U.S. patent claiming the priority to the PCT application WO 2019218024 is granted), Europe, Hong Kong and Australia. Patents issuing from such applications, if any, are expected to expire in May, 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 also have two pending PCT applications, WO 2020000065 and WO 2019222816, 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 have submitted national phase filings in the United States, Europe, Australia, Japan, Canada, and New Zealand. Patents issuing from such applications, if any, are expected to expire in October, 2039, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable.

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

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

We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may own or license in the future, nor can we be sure that any of our existing patents or any patents we may own or license in the future will be useful in protecting our technology. For this and more comprehensive risks related to our intellectual property, please see “Risk Factors—Risks Relating to Protecting Our Intellectual Property.” The term of an individual patent depends upon the legal term of the patent

in the country in which it is obtained. In most countries in which we file, the patent term is 20 years from the date of filing the non-provisional priority application. Because any regulatory approval for a drug often occurs several years after the related patent application is filed, the resulting market exclusivity afforded by any patent on our drug candidates and technologies will likely be substantially less than 20 years. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office ("USPTO") in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent. The term of a U.S. patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. A patent term extension of up to five years may be granted beyond the expiration of the patent. This period is generally one-half of the time between the effective date of an IND (falling after issuance of the patent), and the submission date of an NDA, or BLA, plus the time between the submission date of an NDA and the approval of that application, provided the sponsor acted with diligence. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval and only one patent applicable to an approved drug may be extended. The application for patent term extension is subject to approval by the USPTO in conjunction with the FDA. Due to the specific requirements for obtaining these adjustments and extensions, there is no assurance that our patents will be afforded adjustments or extensions even if we encounter significant delays in patent office proceedings or marketing and regulatory approval.

**Government Regulation**

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

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

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

- completion of extensive preclinical laboratory tests, animal studies and formulation studies in accordance with good laboratory practice ("GLP"), requirements and other applicable regulations;

- submission to the FDA of an 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 Practices ("cGMP") requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA;
- payment of user fees for FDA review of the NDA; and
- FDA review and approval of the NDA to permit commercial marketing or sale of the drug for particular indications for use in the United States.

*Preclinical Studies and Clinical Trials for Drugs*

Before testing any drug in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of drug chemistry, formulation and stability, as well as *in vitro* and animal studies to assess safety and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP requirements for safety/toxicology studies. The results of the preclinical studies, together with manufacturing information and analytical data must be submitted to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before clinical trials may begin. Some long-term preclinical testing may continue even after the IND is submitted. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research patients will be exposed to unreasonable health risks, and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial or to commence a clinical trial with the investigational plan originally specified in the IND.

Clinical trials involve the administration of the product candidate to human subjects under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirements that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters and criteria to be used in monitoring safety and evaluating effectiveness. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development, and for any subsequent amendments to the protocol. Furthermore, an IRB for each institution at

which the clinical trial will be conducted must review and approve the plan for any clinical trial and its informed consent form before the trial begins at that site and must monitor the study until completed. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to the anticipated benefits. Regulatory authorities, including the FDA, as well as the IRB or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Information about applicable clinical trials, including clinical trial results, must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website.

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

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

- Phase 1—Phase 1 clinical trials involve initial introduction of the investigational product into healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2—Phase 2 clinical trials typically involve administration of the investigational product to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages, dose tolerance and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3—Phase 3 clinical trials typically involve administration of the investigational product to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA.

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

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points are generally prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor to obtain the FDA’s feedback on the next phase of development. Sponsors typically use the meetings at the end of the

Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, manufacturers must develop methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA. Written IND safety reports must be submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human volunteers and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

**DEA Regulation**

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

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

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

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

A DEA quota system controls and limits the availability and production of controlled substances in Schedules I and II. Distributions of any Schedule I or II controlled substance must also be accompanied by order

forms, with copies provided to DEA. DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although DEA has substantial discretion in whether or not to make such adjustments.

Individual states also regulate controlled substances.

*U.S. Review and Approval Process for Drugs*

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

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

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

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

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

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

If regulatory approval of a product is granted, such approval will be granted for particular indications and may contain limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a Risk Evaluation and Mitigation Strategy ("REMS") to ensure that the benefits of the drug outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, assessment plans and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk-minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may also require one or more post-approval studies and surveillance, including Phase 4 clinical trials, be conducted to further assess and monitor the product's safety and effectiveness after marketing, and may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

*Orphan Drug Designation and Exclusivity*

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

In addition, if a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity during which the FDA may not approve any other applications to market the same therapeutic agent for the same indication for seven years, except in limited circumstances, such as a subsequent product's showing of clinical superiority over the product with orphan exclusivity or where the original applicant cannot produce sufficient quantities of product. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication than that for which the orphan product has exclusivity. Orphan product exclusivity could also block the approval of one of our products for seven years if a competitor obtains approval for the same therapeutic agent for the same indication before we do, unless we are able to demonstrate that our product is clinically superior. If an orphan designated product receives marketing approval for an indication broader than what is designated, it may

not be entitled to orphan exclusivity. Further, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

*Expedited Development and Review Programs for Drugs*

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

For example, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for such disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a Fast Track designated product has opportunities for more frequent sponsor interactions with the FDA review team during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed, meaning that the agency may review portions of the marketing application before the sponsor submits the complete application, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

In addition, a sponsor may seek FDA designation of a product candidate as a "breakthrough therapy" if the product candidate is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to more intensive FDA interaction and guidance. If a product is designated as Breakthrough Therapy, the FDA will work to expedite the development and review of such drug through FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

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

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

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval do not change the standards for approval but may expedite the development or review process. We may explore some of these opportunities for our product candidates as appropriate.

*Pediatric Information and Pediatric Exclusivity*

Under the Pediatric Research Equity Act ("PREA"), as amended, certain NDAs and certain supplements to an NDA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The FD&C Act requires that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan ("PSP"), within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 trial. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

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

*U.S. Post-Approval Requirements for Drugs*

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products.

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

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing

processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS. Other potential consequences include, among other things:

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

The FDA may also require post-market testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. The FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labeling.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act ("PDMA"), which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

*Marketing Exclusivity*

Market exclusivity provisions under the FD&C Act can delay the submission or the approval of certain marketing applications. The FD&C Act provides a five-year period of non-patent exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is

the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application ("ANDA"), or an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication. However, such an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

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

*Other Regulatory Matters*

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

*Other Healthcare Laws*

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

*Coverage and Reimbursement*

Our ability to successfully commercialize any pharmaceutical product candidate depends, in part, on (1) the extent to which the product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and (2) the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

Third-party payors are increasingly reducing coverage and reimbursement for medical products, drugs and services. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products; and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product.

We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

*Healthcare Reform*

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

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

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

barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures if any, will impact our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, on March 11, 2021, the American Rescue Plan Act of 2021 was signed 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 1, 2024. Further, on August 16, 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law. 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 (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated.

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. 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.

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.

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

*Data Privacy and Security Laws*

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality, and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws 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 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.

**Facilities**

Our headquarters are located at 200 Greenhill Road, Eastwood, South Australia 5063, Australia, where we lease approximately 435 square meters of office space. The lease for our headquarters expires in May 31, 2026. We believe that our existing facilities are adequate for our near-term needs. We believe that suitable additional or alternative space would be available if required in the future on commercially reasonable terms.

**Legal Proceedings**

We are not currently a party to any legal proceedings. We are from time to time subject to claims and litigation arising in the ordinary course of business. We intend to defend vigorously against any future claims and litigation.

**Human Capital**

As of June 30, 2022, we had a total of six full time employees, one part-time employee, two full-time consultants (one of which is based in the United States) and three part-time consultants. . None of our employees are represented by any collective bargaining agreements. We believe that we maintain good relations with our employees. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of share-based compensation awards and cash-based performance bonus awards.

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## Management

### Executive Officers and Directors

The following table sets forth the name, age and position of each of our executive officers and directors as of the date of this prospectus.

| Name | Age | Position |
|---|---|---|
| *Executive Officers* | | |
| Errol De Souza, Ph.D. | 69 | Executive Chairman |
| Adrian Hinton | 70 | Acting Chief Financial Officer |
| Liz Doolin | 57 | Vice President Clinical Development |
| Connor Bernstein | 34 | Vice President of Strategy & Corporate Development |
| *Non-Employee Directors* | | |
| Miles Davies | 41 | Director |
| Alan Fisher | 69 | Director |
| Jane Ryan, Ph.D. | 63 | Director |
| Aaron Weaver | 41 | Director |
| David Wilson | 59 | Director |

### Executive Officers

**Errol De Souza, Ph.D.**, has served as a member of our board of directors since February 2008, as our Chairman since November 2016 and as our Executive Chairman since November 2018. From January 2017 to December 2019, Dr. De Souza served as the President and CEO of Neuropore Therapies, a private biopharmaceutical company focused on the discovery and development of novel small therapeutics for the treatment of neurodegenerative diseases. Prior to that, from March 2010 to January 2016, Dr. De Souza served as the President and CEO of Biodel Inc., a biopharmaceutical company traded on Nasdaq that focused on treatments for endocrine disorders. From March 2009 until March 2010, Dr. De Souza was a pharmaceutical and biotechnology consultant. From April 2003 to March 2009, Dr. De Souza was President and CEO of Archemix Corporation, a private biopharmaceutical company. From September 2002 to March 2003, Dr. De Souza was President and CEO of Synaptic Pharmaceuticals, a biopharmaceutical company traded on Nasdaq which was sold to Lundbeck Pharmaceuticals. Over Dr. De Souza's career, he has served in a number of high-ranking R&D roles, including Senior Vice President and U.S. Head of R&D for Aventis from 1998 to 2002, co-founder and EVP of R&D at Neurocrine from 1992 to 1998 and Head of CNS at DuPont Merck from 1990 to 1992. Dr. De Souza currently serves on the board of several publicly-traded companies, including Catalyst Biosciences, a biopharmaceutical company, since August 2014; Cyclerion Therapeutics, a biopharmaceutical company, since April 2021; and Royalty Pharma, a company that acquires pharmaceutical royalties across the life sciences industry, since October 2008. He has also previously served on the board of directors of IDEXX Laboratories, Inc., a publicly-traded diagnostic company and Palatin Technologies and Neurocrine Biosciences, two publicly-traded biopharmaceutical companies. Dr. De Souza received his Bachelor's degree in physiology and his Ph.D. in neuroendocrinology from the University of Toronto, Canada and he received his postdoctoral fellowship in neuroscience from The Johns Hopkins University School of Medicine. Dr. De Souza's knowledge of our business and significant experience as a biopharmaceutical executive and board member contributed to our board of directors' conclusion that he should serve as a director of our company.

**Adrian Hinton** has served as our Acting Chief Financial Officer since May 2019. Mr. Hinton has served as an accounting consultant for various companies since July 2018. Prior to that, Mr. Hinton worked at Deloitte from January 1975 to July 2018, retiring in July 2018 as Principal in the Audit and Assurance Group. Mr. Hinton has served on the board of the Multiple Sclerosis Society of South Australia and Northern Territory Inc. since November 2016, Carers Association of SA Inc. since May 2019 and Australian PNG Alliance Group Pty Ltd. since October 2018. Mr. Hinton also served on the Audit and Risk Committee of the University of South

Australia from February 2019 to February 2021. Mr. Hinton received his Bachelor's degree in economics from the University of Adelaide, Australia and is a Fellow of the Chartered Accounts Australia and New Zealand.

**Liz Doolin** has served at Bionomics Limited since 2008 and as our Vice President of Clinical Development since 2018. Prior to joining Bionomics, Ms. Doolin served as the Project Manager of Drug Development at New World Bio Limited, an Australian private biotechnology company developing lipid-based therapeutics. Ms. Doolin was previously a research scientist in New Zealand specializing in immunology and protein biotechnology, and a bioprocess development scientist for a biopharmaceutical company in the United Kingdom. Ms. Doolin received her B.Sc. and M.Sc. from the University of Waikato, New Zealand.

**Connor Bernstein** has served as our Vice President of Strategy and Corporate Development since April 2021. Mr. Bernstein has also served as a Principal (Healthcare) of Apeiron Investment Group since January 2021 and a Corporate Development Advisor of Link Immunotherapeutics, a private biotechnology company focused on developing immune engaging combination oncology therapies, since November 2019. From January 2020 to October 2020, Mr. Bernstein was a Corporate Development Advisor of Circumvent Pharmaceuticals, a private pharmaceutical company focused on developing treatments for the significant unmet need of neurodegenerative disease patients. Prior to that, Mr. Bernstein was a Vice President of Investment Banking at RBC Capital Markets from January 2018 to October 2019 and a Senior Associate of Investment Banking from June 2017 to December 2017. Mr. Bernstein has also served as an Investment Banking Associate at Perella Weinberg Partners from July 2016 to March 2017 and Guggenheim Partners, from August 2015 to July 2016, and an Investment Banking Analyst at Piper Jaffray (now Piper Sandler) from June 2013 to August 2015. Mr. Bernstein received his B.A. from the University of California, Santa Cruz, and his B.S. and M.Sc. from the University of Southern California.

**Non-Employee Directors**

**Peter Miles Davies** has served as a member of our board of directors since July 2021. Mr. Davies has worked at Apeiron Investment Group Ltd in the Healthcare team since February 2021. Prior to that, Mr. Davies was at Rothschild & Co. from 2006 to February 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 raisings and restructuring transactions, which all contributed to our board of directors' conclusion that he should serve as a director of our company.

**Alan Fisher** has served as a member of our board of directors since September 1, 2016. He is also Chair of the Audit and Risk Management Committee and a member of the Nomination and Remuneration Committee. Mr. Fisher has served as the Managing Director of Fisher Corporate Advisory Pty Ltd. since 1997, where he advises public and private companies on mergers and acquisitions, public and private equity raisings, business restructuring and strategic advice. He currently serves on the board of several ASX-listed companies, including Centrepoint, Alliance Limited (Chair), a financial licensee, funds management and advice services provider since 2015; IDT Australia Limited (Chair), a developer and manufacturer of pharmaceutical products, since 2015; Thorney Technologies Limited (Non-Executive Director – Chair of Audit and Risk Management Committee), an investment company, since 2016; and Simavita Limited, a medical technology company focused on the development of platform technologies, since 2019. Mr. Fisher served as a Corporate Finance Partner of Coopers & Lybrand from 1974 to 1997. Mr. Fisher received his B.Com., Accounting from the University of Melbourne, Australia and is a Fellow of the Australian and New Zealand Institute of Chartered Accountants. Mr. Fisher's experience as a biopharmaceutical board member and with financing and related transactions across industries contributed to our board of directors' conclusion that he should serve as a director of our company.

**Jane Ryan, Ph.D.** has served as a member of our board of directors since October 2020. Dr. Ryan is a member of the Audit and Risk Management Committee and a member of the Nomination and Remuneration Committee. Since January 2014, Dr. Ryan has provided executive level advisory services to biotechnology companies in connection with capital raising, business development, and mergers and acquisitions. In this capacity, she has served as a commercial and product development advisor to BCAL Diagnostics, a cancer

diagnostics company listed on the ASX, since March 2021. 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 Holdings, a biotechnology company which was listed on the ASX, where she provided oversight to Biota Holdings' development portfolio and programs. Dr. Ryan has served as a director of Anatara Lifesciences since August 2018 and IDT Australia Limited since January 2022, both listed companies. 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.

**Aaron Weaver** has served as a member of our board of directors since July 2020. Mr. Weaver served as a Principal and Head of Capital Markets at Apeiron Investments since June 2021 and May 2019, respectively, where he has focused on the life sciences sector. Prior to that, he served as Senior General Counsel and Lead, Investor Relations, at atai Life Sciences AG, a clinical-stage biopharmaceutical company focused on the development of therapeutics for the treatment of mood disorders, addiction and anxiety, from May 2019 to June 2021. He is a Chartered Financial Analyst and a registered solicitor in the United Kingdom. From June 2013 to August 2017, he was an investment banker at Credit Suisse in London within the Capital Markets Solutions team. He was a capital markets solicitor at Allen & Overy LLP, London from June 2007 to June 2013. Mr. Weaver received his Masters of Law from the Queensland University of Technology and a Bachelor's of Business Administration and Bachelors of Laws from the University of Queensland. Mr. Weaver's experience in capital markets and corporate governance and experience in the healthcare industry contributed to our board of directors' conclusion that he should serve as a director of our company.

**David Wilson** has served as a member of our board of directors since June 2016. He is also Chair of the Nomination and Remuneration Committee and a member of the Audit and Risk Management Committee. He has served as the Chairman and CEO 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 Jeffrey 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 and Election of Directors**

Our board of directors currently consists of six members, including Dr. De Souza, our Executive Chair. Our board of directors may fix the number of directors, provided that there must be at least three and no more than twelve. In accordance with our Constitution, at each annual general meeting, one-third of our directors (other than the Executive Chair, who in substance fulfils the role of Managing Director) must retire from office and their positions be open to election. The retiring directors are eligible for re-election to our board of directors. If the number of directors subject to retirement is not equal to three, or a multiple of three, then the number nearest to, but not exceeding, one-third must retire from office. The directors who retire in this manner are required to be the directors longest in office since last being elected. In addition, each director (other than the Executive Chair) must retire at the later of the third annual general meeting after his or her election or three years after such director was last appointed.

The table below shows the year in which each of our non-executive directors was most recently re-elected and the year he or she must retire from our board of directors, with his or her position up for re-election (with retiring directors eligible for re-election).

| | Year Most Recently Elected | Year Required to Retire |
|---|---|---|
| Miles Davies | 2021 | 2024 |
| Alan Fisher(1) | 2019 | 2022 |
| Jane Ryan, Ph.D. | 2020 | 2023 |
| Aaron Weaver | 2020 | 2023 |
| David Wilson | 2021 | 2024 |

(1) Alan Fisher was appointed to our board of directors at the annual general meeting held in 2019. In accordance with the terms of our Constitution, Mr. Fisher must retire as a director and stand for re-election by shareholders at the Company's 2022 Annual General Meeting on November 16, 2022.

On July 1, 2021, we entered into an employment agreement with Dr. De Souza with a three year term expiring June 30, 2024. On expiry of the initial three-year term and on each yearly anniversary thereof, the employment agreement will automatically renew for an additional one-year period, unless terminated earlier in accordance with the provisions of the agreement or by notice of non-renewal given at least 120 days prior to the end of the initial three-year term. Dr. De Souza does not stand for re-election by our shareholders.

**Board Leadership Structure**

Our board of directors is currently led by our Executive Chairman, Dr. De Souza.

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.

**Director Independence**

As a foreign private issuer, under the listing requirements and rules of Nasdaq, we are not required to have independent directors on our board of directors, except to the extent that our Audit and Risk Management Committee is required to consist of independent directors, subject to certain phase-in schedules. However, our board of directors has determined that all of our directors, other than Dr. De Souza, 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.

In addition, our board of directors has determined that three of our non-executive directors satisfy the independence criteria recommended by the ASX Corporate Governance Principles and Recommendations. These Principles and Recommendations suggest that a director of a listed entity should only be characterized and described as an independent director if he or she is free of any interest, position or relationship that might influence, or reasonably be perceived to influence, in a material respect their capacity to bring an independent judgment to bear on issues before the board and to act in the best interests of the entity as a whole rather than in the interests of an individual security holder or other party. Directors are also required to comply with the general duties of a director imposed under Australian law by the Corporations Act and the common law applicable in Australia.

**Board Responsibilities**

The board of directors is our governing body, responsible for overseeing our executive leadership team in the competent and ethical operation on a day-to-day basis and assuring that the long-term interests of our shareholders are being served. Our board of directors has established delegated limits of authority, which define the matters that are delegated to management and those that require Board approval.

The responsibilities of our board of directors include:

- charting our strategic direction, approving corporate objectives in line with that strategic direction and monitoring progress towards Board approved objectives;
- approving our statement of core values and Code of Business Conduct to underpin the desired culture within the company;
- overseeing management in its implementation of our strategic objectives and instilling our values and performance generally;
- ensuring that our remuneration policies are aligned with our purpose, values, strategic objectives and risk appetite;
- monitoring compliance with regulatory requirements and ethical standards; and;
- appointing and reviewing the performance and remuneration of the Executive Chair.

Our board of directors seeks to ensure that it is cognizant of our state of development such that at any point in time its membership as a group has expertise in areas of current and future importance to us as we grow.

Periodically, our board of directors undertakes a performance evaluation of itself that:

- compares the performance of our board of directors with the requirements of our Board Charter;
- involves the Executive Chair meeting individually with each member of our board of directors to assess how Board performance may be improved; and
- effects any improvements to the Board Charter deemed necessary or desirable.

The board of directors has also typically undertaken a strategic review process once per year to review the corporate strategy and the role of our board of directors within that strategy.

**Board Committees**

Our board of directors currently has two committees, the Audit and Risk Management Committee and the Nomination and Remuneration Committee. Each of the existing members of the Audit and Risk Management Committee and Nomination and Remuneration Committee satisfy the independence requirements under Nasdaq rules and the independence recommendations set out in the ASX Corporate Governance Council's Principles and Recommendations.

***Audit and Risk Management Committee***

The Audit and 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;
- 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), Mr. David Wilson 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 and Mr. David Wilson both qualify as an "audit committee financial expert" as defined by applicable SEC rules and have the requisite financial sophistication as defined under the applicable Nasdaq rules and regulations.

***Nomination and Remuneration Committee***

The primary purpose of the Nomination and Remuneration Committee is to support and advise our board of directors by:

- establishing and assisting in carrying out any processes it considers appropriate for the identification of suitable candidates for appointment to our board of directors and its committees;
- providing recommendations to our board of directors on director appointments and re-elections;
- providing recommendations to our board of directors on appointments to each of its committees;
- making recommendations to our board of directors with respect to our remuneration philosophy, the remuneration of our directors and executive officers, the administration of our equity-based plans and such other matters relating thereto as shall be delegated from time to time by our board of directors; and
- in association with the Executive Chair, providing a talent and succession plan for executives.

The members of our Nomination and Remuneration Committee are currently Mr. David Wilson (Chair), Mr. Alan Fisher and Dr. Jane Ryan. 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 Nomination and Remuneration Committee operates under a written charter, which provides that it will undertake an annual review and evaluation of the performance of our board of directors and its committees and present to our board of directors the results of its review.

**Compensation Committee Interlocks**

None of the members of the Nomination and Remuneration Committee has ever been one of our officers or employees. Except for our Executive Chair, Dr. De Souza, 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 Executive Chair, 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.bionomics.com.au*. 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 prospectus.

**Remuneration**

Our remuneration policy aims to align director and executive objectives with shareholder and business objectives by providing a fixed remuneration component and typically offering long-term incentives based on key performance areas. Our board of directors believes the remuneration policy to be appropriate and effective in its ability to attract and retain the best executives and directors to run and manage the consolidated entity, as well as create goal congruence between directors, executives, and shareholders. Our board of directors reviews and approves remuneration package for our executives, including our Executive Chairman, recommended by the Nomination and Remuneration Committee.

***Director Compensation***

Non-executive directors' fees are determined within a shareholder approved aggregate non-executive directors' fee pool limit. The non-executive directors' fee pool is reviewed by our board of directors and submitted to shareholders for approval from time to time, taking into account comparable remuneration data for the biotechnology sector provided by an independent remuneration consultancy. The current aggregate non-executive directors' fee pool limit is A$750,000 per annum and was approved by shareholders at the Extraordinary General Meeting on August 26, 2020. This amount (or a portion thereof) is to be divided among the non-executive directors as determined by our board of directors and reflecting the time and responsibility related to our board of directors and its committees.

For the fiscal year ending June 30, 2022, non-executive directors' fees were A$77,000 per annum, inclusive of any statutory Australian superannuation contributions if applicable. The Chair of each committee received an additional A$10,000 per annum, inclusive of any statutory Australian superannuation contributions if applicable, for services relating to such Chair duties. Our Executive Chairman is also a member of our board of directors but did not receive any additional compensation for his service as a director. In addition to an annual fee, non-executive directors may receive share options at the time of their initial appointment to our board of directors or at other times, as approved by shareholders. Any value attributable to options issued to non-executive directors is not counted towards the non-executive directors' fee pool limit.

In addition to other remuneration provided, all of our directors are entitled to reimbursement for travel accommodations and other expenses reasonably incurred by the directors in attending general meetings, board meetings, committee meetings or otherwise in connection with our business. Other than any statutory Australian superannuation contributions, we do not provide retirement allowances to our non-executive directors.

The aggregate cash remuneration paid to non-executive directors for the fiscal year ending June 30, 2022 was A$48,591 plus an additional aggregate superannuation retirement contribution of A$14,909.

***Executive Compensation***

The objective of our executive remuneration policy and framework is to ensure that we can attract and retain high caliber executives capable of managing our operations and achieving our strategic objectives and focus

these executives on outcomes necessary for success. The executives' total remuneration package framework is comprised of a combination of:

- base pay and benefits, including for Australian employees a superannuation retirement contribution and other entitlements;
- short-term performance incentives that may be paid as shares, share options, cash or a combination thereof; and
- long-term performance incentives through participation in our employee equity plans.

Upon recommendation by the Nomination and Remuneration Committee, our board of directors reviews and approves the base pay, benefits, incentive payments and equity awards of the Executive Chair and other executives who report directly to the Executive Chair.

Executives receive their base pay and benefits structured as a Total Fixed Remuneration ("TFR") package which may be delivered as a combination of cash and prescribed nonfinancial benefits at the executives' discretion. Superannuation (or local equivalent) is included in TFR. There are no guaranteed base pay increases in any executive contract.

Base pay and benefit levels are reviewed annually by the Nomination and Remuneration Committee, and includes an assessment made against market comparable positions. Factors taken into account in determining an executive's remuneration include remuneration paid to executives with comparable responsibilities, duties and experience to the executive under review by competitive biotechnology companies, the executive's demonstrated record of performance, internal relativities, and the company's capacity to pay. An executive's base pay and benefit levels may also be reviewed if the position's accountabilities increase in scope and impact.

Other than for our Executive Chairman, executive positions have no pre-determined bonus or equity opportunity; however, performance incentives may be awarded 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 incentive payable to each executive is determined by our board of directors based on the Executive Chair's recommendation. Our board of directors determines whether the incentive award should be in share options, shares and/or cash.

**Key Terms of Executive Employment Agreements**

Remuneration and other terms of employment for the Executive Chairman and the other executives are formalized in the form of an executive employment contract or consultancy agreement. No transaction or other bonuses or amounts will be triggered by the consummation of this offering. Major provisions of the agreements relating to remuneration are set out below:

*Dr. Errol De Souza, Executive Chairman*

Effective July 1, 2021, we entered into an Executive Employment Agreement with Dr. De Souza for the position of Executive Chairman, replacing all prior arrangements. The Executive Employment Agreement became effective on July 1, 2021, and has a term ending on June 30, 2024. Under this agreement, Dr. De Souza receives fixed remuneration of $43,750 base salary per month (plus reimbursement of health care benefits of up to $22,000 for the first year of employment, and subsequently adjusted based on documented increases) for the provision of executive services as determined by our board of directors, plus a short-term incentive/bonus potential of 60% of the base salary upon meeting the applicable performance criteria established by the Nomination and Remuneration Committee against agreed financial, strategic and operational targets (the "De Souza Target Bonus"). For performance exceeding such applicable performance criteria, the Nomination and

Remuneration Committee, in its sole discretion, may increase the short-term incentive/bonus up to 100% of the base salary. In addition, effective July 1, 2021, Dr. De Souza received a grant of 47,786,607 options with an exercise price per share equal to A$0.2014, which award will vest on a quarterly basis over a four-year period commencing on July 1, 2021 (with acceleration in the event of a change in control and also on termination as described below) (the "Employment Options"). The award was subject to shareholder approval, which was obtained at the 2021 Annual General Meeting.

The Executive Employment Agreement with Dr. De Souza may be terminated by either party. In the event of a termination of the agreement by the company for cause, the company will pay earned but unpaid base salary, unreimbursed business expenses and any amounts or benefits entitled under the benefits plans of the company. In the event of Dr. De Souza's voluntary resignation without good reason, he will provide six months' notice. In the event of a termination without cause, redundancy or resignation for good reason, (a) the company will pay severance of 12 months of base salary plus a pro rata amount of the target bonus potential to be paid in equal instalments over the following 12-month period; (b) any outstanding equity compensation awards will fully and immediately vest with respect to any amounts that would have vested as if remaining employed for an additional 24 months; and (c) any termination benefits in excess of the limits in the Corporations Act are subject to shareholder approval.

*Mr. Adrian Hinton, Acting Chief Financial Officer*

The company entered into a Consultancy Agreement with Adrian Hinton to perform the duties of Acting Chief Financial Officer. The Consultancy Agreement is subject to termination by either party on one months' notice. By a letter agreement dated July 23, 2022, Mr. Hinton's fees payable under the Consultancy Agreement were changed to A$21,000 (plus goods and services tax) per month for the period commencing July 1, 2022 until June 30, 2023, and the term of the agreement was extended through such date. All other terms of the Consultancy Agreement remain the same.

*Ms. Liz Doolin, Vice President Clinical Development*

The company has entered into a services agreement with Liz Doolin to perform the duties of Vice President, Clinical Development. The agreement does not have a specified term. Ms. Doolin's total remuneration package is reviewed annually by the Executive Chairman and Managing Director and approved by the Board. The agreement is subject to termination by either party on one months' notice. By a letter dated July 1, 2022, Ms. Doolin's salary was increased to A$243,000 for the fiscal year ending June 30, 2023.

*Mr. Connor Bernstein, Vice President Strategy and Corporate Development*

The company has entered into a Consultancy Agreement with Connor Bernstein, of JB Strategy Partners LLC, to perform the duties of Vice President, Strategy and Corporate Development, which agreement had a term commencing April 1, 2021 and ending March 31, 2022. The company subsequently agreed to extend the term of Mr. Bernstein's Consultancy Agreement through June 30, 2023. Under the agreement, Mr. Bernstein receives a consulting fee of $22,500 per month. The Consultancy Agreement is subject to termination by either party on three months' notice.

For the fiscal year ended June 30, 2022, the Nomination and Remuneration Committee made recommendations to the Board, which approved the De Souza Target Bonus, the IPO Options (as defined below), and discretionary initial public offering (IPO) cash bonus awards in relation to work performed for the IPO (each, a "Discretionary IPO Bonus") and Discretionary STIA awards to our executives (other than our Executive Chairman) for the 2022 financial year. All Discretionary IPO Bonuses and Discretionary STI Awards were

awarded in cash. The following table indicates the awards received by our executive officers during the fiscal year ended June 30, 2022:

| Executive KMP | Position | Award | STI Achievement | Value $ |
|---|---|---|---|---|
| Dr. Errol De Souza | Executive Chairman | De Souza Target Bonus (60% of Base Salary) | 100% | $315,000 |
| | | IPO Options[(i)] [(ii)] | — | A$1,311,119 |
| Mr. Adrian Hinton | Acting Chief Financial Officer | Discretionary STI Award | — | A$36,000 |
| | | Discretionary IPO Bonus | — | A$40,000 |
| Mr. Connor Bernstein | Vice President Strategy and Corporate Development | Discretionary STI Award | — | $33,750 |
| Ms. Liz Doolin | Vice President Clinical Development | Discretionary STI Award | — | A$34,500 |

(i) In connection with and contingent upon our initial public offering and shareholder approval obtained at the 2021 Annual General Meeting, Dr. De Souza received a grant of options (the "IPO Options") to purchase 13,430,160 shares at an exercise price of $0.09645 per share. Subject to Dr. De Souza's continued service with the company, the IPO Options will vest in 16 substantially equal installments on the last day of each calendar quarter over the 4-year period commencing on January 1, 2022, with the first such installment vesting on March 31, 2022. The IPO Options are further subject to acceleration in the event of a change in control and also on termination, as described in the section describing his Executive Employment Agreement above.

(ii) In connection with the IPO Options, the fair value of the equity issued for no cash consideration is recognized as a share-based payment expense with a corresponding increase in equity over the vesting period. Information about how the fair value was calculated for share options issued during the year is set out in Note 21 to our audited consolidated financial statements included within our Annual Report on Form 20-F for the fiscal year ended June 30, 2022, which is incorporated by reference in this prospectus.

The IPO bonus options were issued on December 22, 2021, and details of the award are set out below:

| Number | Grant date | Expiry date | Exercise price | Vesting date | Fair value |
|---|---|---|---|---|---|
| 839,385 | 2-Dec-21 | 31-Mar-27 | A$ 0.0965 | 31-Mar-22 | A$ 75,545 |
| 839,385 | 2-Dec-21 | 30-Jun-27 | A$ 0.0965 | 30-Jun-22 | A$ 76,384 |
| 839,385 | 2-Dec-21 | 30-Sep-27 | A$ 0.0965 | 30-Sep-22 | A$ 77,223 |
| 839,385 | 2-Dec-21 | 31-Dec-27 | A$ 0.0965 | 31-Dec-22 | A$ 78,902 |
| 839,385 | 2-Dec-21 | 31-Mar-28 | A$ 0.0965 | 31-Mar-23 | A$ 79,742 |
| 839,385 | 2-Dec-21 | 30-Jun-28 | A$ 0.0965 | 30-Jun-23 | A$ 80,581 |
| 839,385 | 2-Dec-21 | 30-Sep-28 | A$ 0.0965 | 30-Sep-23 | A$ 81,420 |
| 839,385 | 2-Dec-21 | 31-Dec-28 | A$ 0.0965 | 31-Dec-23 | A$ 82,260 |
| 839,385 | 2-Dec-21 | 31-Mar-29 | A$ 0.0965 | 31-Mar-24 | A$ 82,260 |
| 839,385 | 2-Dec-21 | 30-Jun-29 | A$ 0.0965 | 30-Jun-24 | A$ 83,099 |
| 839,385 | 2-Dec-21 | 30-Sep-29 | A$ 0.0965 | 30-Sep-24 | A$ 83,938 |
| 839,385 | 2-Dec-21 | 31-Dec-29 | A$ 0.0965 | 31-Dec-24 | A$ 84,778 |
| 839,385 | 2-Dec-21 | 31-Mar-30 | A$ 0.0965 | 31-Mar-25 | A$ 85,617 |
| 839,385 | 2-Dec-21 | 30-Jun-30 | A$ 0.0965 | 30-Jun-25 | A$ 85,617 |
| 839,385 | 2-Dec-21 | 30-Sep-30 | A$ 0.0965 | 30-Sep-25 | A$ 86,457 |
| 839,385 | 2-Dec-21 | 31-Dec-30 | A$ 0.0965 | 31-Dec-25 | A$ 87,296 |
| 13,430,160 | | | | | A$ 1,311,119 |

The following table indicates the remuneration received by our non-executive directors and executive officers during the fiscal year ending June 30, 2022:

| | Cash Salary and Fees (A$) | Bonus (A$) | Superannuation (A$) | Annual and Long Service Leave (A$) | Options[1][2] (A$) | Total (A$) |
|---|---|---|---|---|---|---|
| **Non-Executive Directors** | | | | | | |
| Alan Fisher | 79,091 | — | 7,909 | — | — | 87,000 |
| David Wilson | 87,000 | — | — | — | — | 87,000 |
| Jane Ryan, Ph.D. | 70,000 | — | 7,000 | — | 16,146 | 93,146 |
| Aaron Weaver | 77,000 | — | — | — | — | 77,000 |
| Miles Davies(3) | 77,000 | — | — | — | — | 77,000 |
| Mitchell Kaye(4) | 38,500 | — | — | — | — | 38,500 |
| **Executive Officers** | | | | | | |
| Errol De Souza, Ph.D. | 768,002[5] | 456,214[6] | — | — | 2,802,987 | 4,027,203 |
| Adrian Hinton | 218,182 | 76,000[7] | 29,598 | — | — | 323,780 |
| Liz Doolin | 209,091 | 34,500[8] | 24,532 | 22,241 | — | 290,364 |
| Connor Bernstein | 226,898 | 118,081[9] | — | — | — | 344,979 |
| | **1,850,764** | **684,795** | **69,039** | **22,241** | **2,819,133** | **5,445,972** |

(1) Share options do not represent cash payments to directors and other key management personnel. Share options granted may or may not be exercised by directors and other key management personnel.
(2) The amounts relate to amortization of share options granted over the vesting period.
(3) Mr. Davis was appointed July 1, 2021.
(4) Mr. Kaye resigned on December 31, 2021.
(5) Comprises Executive Chair's consultancy fee of A$737,114 and reimbursement of health insurance of A$38,888.
(6) Relating to De Souza Target Bonus of $315,000 (A$456,214).
(7) Relating to year ended 2022 Discretionary STI Awardof A$36,000 and a Discretionary IPO-Bonus of A$40,000.
(8) Relating to year ended 2022 Discretionary STI Award of A$34,500.
(9) Relating to year ended 2022 Discretionary STI Award of $33,750 (A$48,880) and a Discretionary IPO Bonusof $50,000 (A$69,201).

The following table sets forth the number of options granted in the fiscal year ending June 30, 2022, their vesting conditions, their exercise price and the applicable expiration date:

| Name | Number of Ordinary Share Options | Vesting Conditions | Exercise price | Expiration Date |
|---|---|---|---|---|
| Dr. Errol De Souza | 2,986,663[1] | (2) | A$0.2014 | September 30, 2026 |
| Dr. Errol De Souza | 2,986,663[1] | (2) | A$0.2014 | December 31, 2026 |
| Dr. Errol De Souza | 2,986,663[1] | (2) | A$0.2014 | March 31, 2027 |
| Dr. Errol De Souza | 2,986,663[1] | (2) | A$0.2014 | June 30, 2027 |
| Dr. Errol De Souza | 2,986,663[1] | (2) | A$0.2014 | September 30, 2027 |
| Dr. Errol De Souza | 2,986,663[1] | (2) | A$0.2014 | December 31, 2027 |
| Dr. Errol De Souza | 2,986,663[1] | (2) | A$0.2014 | March 31, 2028 |
| Dr. Errol De Souza | 2,986,663[1] | (2) | A$0.2014 | June 30, 2028 |
| Dr. Errol De Souza | 2,986,663[1] | (2) | A$0.2014 | September 30, 2028 |
| Dr. Errol De Souza | 2,986,663[1] | (2) | A$0.2014 | December 31, 2028 |
| Dr. Errol De Souza | 2,986,663[1] | (2) | A$0.2014 | March 31, 2029 |
| Dr. Errol De Souza | 2,986,663[1] | (2) | A$0.2014 | June 30, 2029 |
| Dr. Errol De Souza | 2,986,663[1] | (2) | A$0.2014 | September 30, 2029 |

| Name | Number of Ordinary Share Options | Vesting Conditions | Exercise price | Expiration Date |
|---|---|---|---|---|
| Dr. Errol De Souza | 2,986,663[1] | (2) | A$0.2014 | December 31, 2029 |
| Dr. Errol De Souza | 2,986,663[1] | (2) | A$0.2014 | March 31, 2030 |
| Dr. Errol De Souza | 2,986,663[1] | (2) | A$0.2014 | June 30, 2030 |
| Dr. Errol De Souza | 839,385[3] | (2) | A$0.0965 | March 31, 2027 |
| Dr. Errol De Souza | 839,385[3] | (2) | A$0.0965 | June 30, 2027 |
| Dr. Errol De Souza | 839,385[3] | (2) | A$0.0965 | September 30, 2027 |
| Dr. Errol De Souza | 839,385[3] | (2) | A$0.0965 | December 31, 2027 |
| Dr. Errol De Souza | 839,385[3] | (2) | A$0.0965 | March 31, 2028 |
| Dr. Errol De Souza | 839,385[3] | (2) | A$0.0965 | June 30, 2028 |
| Dr. Errol De Souza | 839,385[3] | (2) | A$0.0965 | September 30, 2028 |
| Dr. Errol De Souza | 839,385[3] | (2) | A$0.0965 | December 31, 2028 |
| Dr. Errol De Souza | 839,385[3] | (2) | A$0.0965 | March 31, 2029 |
| Dr. Errol De Souza | 839,385[3] | (2) | A$0.0965 | June 30, 2029 |
| Dr. Errol De Souza | 839,385[3] | (2) | A$0.0965 | September 30, 2029 |
| Dr. Errol De Souza | 839,385[3] | (2) | A$0.0965 | December 31, 2029 |
| Dr. Errol De Souza | 839,385[3] | (2) | A$0.0965 | March 31, 2030 |
| Dr. Errol De Souza | 839,385[3] | (2) | A$0.0965 | June 30, 2030 |
| Dr. Errol De Souza | 839,385[3] | (2) | A$0.0965 | September 30, 2030 |
| Dr. Errol De Souza | 839,385[3] | (2) | A$0.0965 | December 31, 2030 |

(1) The options are part of Dr. De Souza's Employment Options grant.
(2) Vesting is subject to Dr. De Souza remaining an employee or director of the Company or one of its subsidiaries at the time of each vesting date. Each option is further subject to acceleration in the event of a change in control and also on termination, as described in the section describing his Executive Employment Agreement above.
(3) The options are part of Dr. De Souza's IPO Options grant.

**Equity Awards**

Equity awards for executives and employees are provided by a combination of equity plans and include the:

- Employee Share Plan (A$1,000 Plan);
- Employee Share Option Plan; and
- Employee Equity 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 Nomination & Remuneration 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.

***Employee Share Plan ("A$1,000 Plan")***

The objective of the A$1,000 Plan is to assist us in the attraction and retention of employees, and to provide encouragement to become shareholders. An annual allocation of up to A$1,000 of shares may be granted and taxed on a concessional basis. No shares were issued to employees under the A$1,000 Plan during the fiscal year ended June 30, 2022.

| | |
|---|---|
| Eligibility | All our full-time employees or part-time employees or a related body corporate who have been employed for a period of not less than 12 months (or such shorter period as our board of directors may determine) or directors may participate in the A$1,000 Plan, referred to as A$1,000 Plan Eligible Employees. |
| Administration of A$1,000 Plan | The A$1,000 Plan is managed by our board of directors, which has the power to determine the appropriate procedures for the administration of the A$1,000 Plan. |
| Invitation | Our board of directors may make an invitation to an A$1,000 Plan Eligible Employee to apply for ordinary shares under the A$1,000 Plan on such terms and conditions as our board of directors determines from time to time, including (i) the date at which the value of shares will be used to determine the number of shares to be issued to the A$1,000 Plan Eligible Employee (up to the value of A$1,000); (ii) the last date for acceptance of the invitation; (iii) the manner in which the invitation may be accepted; and (iv) any conditions which must be satisfied or circumstances which must exist before all or any of the shares are issued. |
| Issue price | No consideration is payable by an A$1,000 Plan Eligible Employee to subscribe for shares offered under the A$1,000 Plan. |
| Holding lock | Subject to the ASX Listing Rules, we will procure our share registry to apply a holding lock on a participant's shares for the period of three years from the date the shares are issued ("Holding Period"). Without the consent of the Board, a participant must not assign, transfer or otherwise deal with their shares for the duration of the Holding Period. |
| Rights attaching to shares | *Ranking.* Shares issued under the A$1,000 Plan rank equally with all our other fully paid ordinary shares at the time of issue.<br><br>*Dividends.* Holders of shares granted under the A$1,000 Plan are entitled to participate in dividends declared and paid by us.<br><br>*Voting rights*. Holders of shares granted under the A$1,000 Plan are entitled to exercise all voting rights attached to the shares in accordance with our Constitution.<br><br>*New and bonus issues*. Holders of shares granted under the A$1,000 Plan have the same right to participate in new and bonus issues of shares as conferred on other shareholders. |
| Amendments to the A$1,000 Plan | Our board of directors may at any time by resolution amend any provision of the A$1,000 Plan. However, no amendment may be made if the amendment materially prejudices the rights of any participant as they existed before the date of the relevant amendment. |
| Termination or suspension of A$1,000 Plan | Our board of directors may terminate or suspend the operation of the A$1,000 Plan at any time. Termination or suspension of the A$1,000 Plan will not prejudice the accrued rights of participants. |

***Employee Share Option Plan ("ESOP")***

The ESOP was approved by our board of directors in 2014 and last approved by shareholders at the 2014 Annual General Meeting. The ESOP has now been superseded by the Employee Equity Plan (see below). No options were issued under the ESOP during the financial year to June 30, 2022.

| | |
|---|---|
| Eligibility | All our full or part-time employees who have been employed for a period of not less than six months (or such shorter period as our board of directors may determine) and all directors are eligible to participate in the ESOP, referred to as ESOP Eligible Participants. |
| Administration of ESOP | The ESOP is administered by our board of directors which may, subject to the Corporations Act and the ASX Listing Rules, revoke or amend the terms of the ESOP and suspend or terminate the ESOP. |
| Invitation | Our board of directors may invite ESOP Eligible Participants to take up share options under the ESOP for no consideration. The Board has the sole discretion to determine which ESOP Eligible Participants will receive invitations and when those invitations will be made. |
| Exercise price | Unless our board of directors determines otherwise, the exercise price of share options granted under the ESOP will be the volume weighted average closing price of our ordinary shares traded on the ASX for the seven trading days immediately preceding the date on which the invitation is made. |
| Exercise period | Unless the Board determines otherwise, share options will become exercisable as to 1/5 of the share options each year over a five year period on each anniversary of acceptance of the invitation relating to those share options. |
| Lapse of share options | The share options will have a term of five years from the date they first become exercisable, and if not then exercised will lapse at the end of the applicable exercise period. However, if the ESOP Eligible Participant ceases to be an ESOP Eligible Participant for any reason, other than by death, retrenchment or retirement, then (i) any share options held by that participant for which the exercise period has commenced will lapse 30 days after the date the participant ceased to be an ESOP Eligible Participant; and (ii) any share options held by that participant for which the exercise period has not commenced will lapse on the date the participant ceased to be an ESOP Eligible Participant. |
| Shares issued | Upon the exercise of a share option, we will issue a fully paid ordinary share ranking equally with, and having the same rights and entitlements as, our other ordinary shares on issue at the date of allotment of the option share (other than rights and entitlements accrued prior to the date of allotment of the option share). |
| Restrictions on transfer of share options | An ESOP Eligible Participant must not assign or transfer his or her share options (without our consent), other than a transfer of share options to a legal personal representative in the event that an ESOP Eligible Participant has died or become subject to mental health legislation. |
| Share options must be exercised before participation in new share issues | An ESOP Eligible Participant cannot participate in new issues of our shares without first exercising his or her share options. We must give notice of new share issues to each ESOP Eligible Participant who holds share options, other than issues pursuant to the ESOP, the ESP, a private placement, a dividend reinvestment plan, a share purchase plan or a bonus share plan, a rights issue or any other employee share or options plan designated by the Board, applying from time to time. |

**Employee Equity Plan ("EEP")**

The EEP replaces the ESOP. The EEP was last amended by the Board on October 31, 2021 and was drafted to reflect changes to the income tax legislation governing employee share schemes, governance changes in respect of the type of equity instruments that are granted to employees and directors, the circumstances in which they are granted, and to provide administrative flexibility.

The underlying purpose of the EEP is to align employees' and directors' interests with shareholders' interests by providing them with equity as part of their remuneration arrangements. This is designed to enable us to attract and retain top-level employees and directors. The procurement and retention of first-class executives and employees capable of managing our operations and achieving our strategic objectives is always a difficult task for a relatively small company, without an earnings history, such as us. In order to compete with well-established companies, our board of directors considers that we essentially have one of two choices: either offer higher cash remuneration or issue equity under a plan such as the EEP.

The EEP enables our board of directors to award different types of equity instruments tailored to specific application. These can include rights to acquire shares contingent on meeting specified performance metrics, options to acquire shares on payment of an exercise price, rights and/or options that are contingent on remaining in employment, among others.

The EEP was last amended on October 31, 2021 to provide us with increased flexibility to settle EEP awards offered or granted to non-Australian employees and directors by enabling us to offer and grant EEP awards that may be settled in ADS (at a number of ADS that represents the appropriate number of Ordinary Shares offered or granted under the award). In addition, the amendment permits us to (i) determine any monetary amounts and accept payments related to the EEP or awards issued thereunder in United States dollars (or any other currency the Board deems acceptable), (ii) impose terms and conditions on the EEP or awards issued thereunder to comply with the securities and tax laws of the United States (or any other jurisdiction the Board deems appropriate), and (iii) take any other steps the Board deems necessary or desirable to settle EEP awards in ADS.

| | |
|---|---|
| Eligibility | Our board of directors may determine which of our full-time employees, part-time employees or directors who holds a salaried employment or office may participate in the EEP, referred to as EEP Eligible Employees. |
| Administration of EEP | The EEP is managed by our board of directors, which has the power to determine the appropriate procedures for the administration of the EEP. |
| Invitation | Our board of directors may make an invitation to an EEP Eligible Employee to apply for ordinary shares under the EEP on such terms and conditions as our board of directors determines from time to time, including (i) the date of allocation of the shares; (ii) the total number of shares to be allocated; (iii) the issue price per share; (iv) the terms of any loan in relation to the shares; (v) any vesting conditions in relation to the shares; (vi) any events that will require the participant to compulsorily divest the shares; (vii) the effect on the shares and any loan in respect of the shares in the event of any takeover offer or scheme of arrangement in respect of the company; and (viii) any other terms and conditions that, in the opinion of our board of directors, are fair and reasonable and not inconsistent with the EEP. |
| Issue price | The issue price per share granted under the EEP is determined by our board of directors in its sole discretion. |

| | |
|---|---|
| Cap on number of Ordinary Shares to be issued under the EEP | The number of shares offered to participants under the EEP must not, when aggregated with the number of shares issued (and outstanding offers to issue under any employee share scheme) over the prior five years under the EEP or any other employee share scheme extended only to EEP Eligible Employees, exceed 5% of our total number of issued shares at the time the offer is made, excluding certain offers. Examples of excluded offers include those made under a disclosure document or not requiring disclosure due to Section 708 of the Corporations Act of Australia. Our board of directors retains the discretion to increase the cap on the number of the shares to be issued under the EEP, so long as the increase complies with applicable law. |
| Loan | The EEP provides our board of directors with the discretion to invite EEP Eligible Employees to apply for a loan (on terms and conditions determined by the Board) to fund the acquisition of the shares. However, no loans will be made to executive officers in violation of Section 404 of the Sarbanes-Oxley Act. |
| Company's security interest | Where a loan is entered into, we will be granted a security interest over a participant's right, title and interest in their shares, the proceeds of their shares, and any marketable securities resulting from the conversion, consolidation or subdivision of any share. The security interest will remain in place until the loan has been repaid in full. |
| Vesting conditions | Shares may be subject to any vesting condition as the Board determines. Shares will vest in the participant upon all the vesting conditions being satisfied. Our board of directors has discretion to attach individual vesting conditions to the shares at the time they are issued. One or more vesting conditions may be attached to a portion of the shares. Our board of directors may in its absolute discretion waive any or all of the vesting conditions. |
| Holding lock | Subject to the ASX Listing Rules, we will procure our share registry to apply a holding lock on a participant's shares for the period during which any amount of a loan remains outstanding or for the period during which their shares remain unvested. A participant must not dispose of or grant any mortgage, charge, pledge, lien, encumbrance or other third party interest over any shares during such holding lock period, other than a charge given in our favor as security for a loan. |
| Rights attaching to shares | *Ranking*. Shares issued under the EEP rank equally with all our other fully paid ordinary shares at the time of issue.<br><br>*Dividends.* Holders of shares granted under the EEP are entitled to participate in dividends declared and paid by us.<br><br>*Voting rights*. Holders of shares granted under the EEP are entitled to exercise all voting rights attached to the shares in accordance with our Constitution. |
| Amendments to the EEP | Subject to the exceptions listed below, our board of directors may at any time by resolution amend any provision of the EEP. However, no amendment may be made if the amendment materially prejudices the rights of any participant as they existed before the date of the relevant amendment. |

| | |
|---|---|
| | The exceptions are: (i) amendments agreed to in writing by all participants; and (ii) amendments introduced primarily (a) for compliance with new laws or regulations; (b) to correct any manifest error or mistake; (c) to allow the implementation of an employee share trust arrangement in relation to the holding of the shares granted under the EEP; (d) to enable us to comply with our Constitution and any other applicable law or regulation; and/or (e) to take into consideration possible adverse taxation implications in relation to the EEP. |
| Termination or suspension of EEP | Our board of directors may terminate or suspend the operation of the EEP at any time. Termination or suspension of the EEP will not prejudice the accrued rights of participants. |

The following table sets forth the number of options held by non-executive directors and executive officers as of June 30, 2022.

| Name | Balance at June 30, 2021 Number | Granted as compensation Number | Exercised Number | Net other change Number | Balance at June 30, 2021 Number | Balance vested and exercisable at June 30, 2022 Number | Options vested during year Number |
|---|---|---|---|---|---|---|---|
| **Non-Executive Directors** | | | | | | | |
| David Wilson | 500,000 | — | — | — | 500,000 | 500,000 | 100,000 |
| Alan Fisher | 500,000 | — | — | — | 500,000 | 500,000 | 100,000 |
| Jane Ryan Ph.D. | 500,000 | — | — | — | 500,000 | 100,000 | 100,000 |
| Aaron Weaver | — | — | — | — | — | — | |
| Mitchell Kaye[1] | — | — | — | — | — | — | — |
| Miles Davies[2] | — | — | — | — | — | — | — |
| **Executive Officers** | | | | | | | |
| Errol De Souza, Ph.D. | 12,500,000 | 61,216,767[3] | — | — | 73,716,767 | 26,125,422 | 13,725,422 |
| Adrian Hinton | — | — | — | — | — | — | — |
| Liz Doolin | 1,030,000 | — | — | (15,000)[4] | 1,015,000 | 1,015,000 | — |
| Connor Bernstein | — | — | — | — | — | — | — |

(1) Mr. Kaye retired on December 31, 2021.
(2) Mr. Davies was appointed on July 1, 2021.
(3) Dr Errol De Souza received 47,786,607 Employment Options under his Consultancy Agreement and 13,430,160 IPO Options as an IPO bonus, each as approved by shareholders on December 2, 2021.
(4) 15,000 share options held by Ms. Doolin were unexercised as of November 28, 2022 and thereby lapsed under the terms of the applicable award agreement.

**Family Relationships**

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

## Certain Relationships and Related Party Transactions

The following is a summary of each transaction or series of similar transactions since July 1, 2019, or any currently proposed transaction, to which we were or are a party in which:

- the amount involved exceeded or exceeds $120,000; and
- any of our directors or executive officers, any holder of 5% of any class of our voting capital stock 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 Person Transactions

We comply with Australian law (including the Corporations Act) and the ASX Listing Rules regarding approval of transactions with related parties. Our Audit and 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.

### Financings

In November 2018, we entered into a placement agreement (the "BVF Placement Agreement") with BVF pursuant to which we issued 60,169,738 ordinary shares to BVF for an issue price of A$0.1637 on November 16, 2018. BVF purchased an aggregate of 46,977,899 ordinary shares in subsequent entitlement offers to existing stockholders.

In June 2020, we entered into a subscription agreement (the "Apeiron Subscription Agreement") with Apeiron Investment Group Ltd. ("Apeiron") pursuant to which Apeiron agreed to subscribe or procure subscriptions for 135,833,000 ordinary shares at an issue price of A$0.04 per ordinary share to raise A$5,433,320, to proceed in two tranches of 81,500,000 Shares ("First Placement") and 54,333,000 ordinary shares ("Second Placement"), the Second Placement being subject to shareholder approval. The First Placement was completed in June 2020, and the Second Placement was completed in September 2020.

Following completion of the Second Placement, we conducted a pro rata entitlement offer in favor of eligible shareholders (including eligible retail shareholders) and 54,304,446 ordinary shares at A$0.04 per ordinary share (being the same price as the First Placement and Second Placement ("Entitlement Offer"), were issued.

Following completion of the Second Placement, we were also able to issue 272,349,194 ordinary shares pursuant to one or more offers of a nature to be determined by us in our discretion (after consultation in good faith with Apeiron), provided that one of the offers was a pro rata issue (such as an entitlement offer) or security purchase plan offer ("Further Offers").

Apeiron agreed, subject to shareholder and Foreign Investment Review Board ("FIRB") approvals, to underwrite the issue of ordinary shares under any Further Offers ("Underwritten Shares") provided that the price at which ordinary shares are offered under the Further Offer is equal to or greater than A$0.06 per ordinary share and that the total amount of funds raised by us under Further Offers will not exceed A$15,000,000 ("Underwriting Obligation"). On March 3, 2021, we issued 150,000,000 warrants ("Warrants") to Apeiron. Every one Warrant grants Apeiron the right to be issued one further ordinary share at an exercise price of A$0.06. The Warrants expire on August 26, 2023.

On March 2, 2021, we completed a placement of 110,287,131 ordinary shares at an issue price of A$0.145 per share, to raise a total of A$15,991,634 in satisfaction of the Underwriting Obligations. As FIRB had granted Apeiron approval to acquire up to a 52% interest in the Company following the Second Placement in September 2020, and in accordance with the terms of the Subscription Agreement, we issued the Warrants to Apeiron on March 2, 2021.

On March 8, 2021, we announced we were undertaking a 1 for 6 pro rata non-renounceable Entitlement Offer ("Subsequent Entitlement Offer"). On March 17, 2021, we announced we had invited certain investors who participated in our share placement on March 2, 2021, to apply for further new shares, concurrently with the Subsequent Entitlement Offer ("Concurrent Placement"). On April 8, 2021, we issued 140,924,683 ordinary shares at an issue price of A$0.145 under the Subsequent Entitlement Offer to raise a total of A$20,434,079 and issued a further 17,228,346 ordinary shares under the Concurrent Placement, at an issue price of A$0.145, raising A$2,498,110. There was also an additional share placement on June 4, 2021 of 3,909,034 shares at A$0.145, raising A$566,810.

In December 2021, we completed a U.S. IPO of 1,622,000 ADSs, each representing 180 ordinary shares, at an offering price of $12.35 per ADS for aggregate gross proceeds to us of approximately $20.0 million. The net offering proceeds to us, after deducting underwriting discounts and commissions and other offering expenses, were approximately $18.6 million. In January 2022, we sold 243,300 ADSs, each representing 180 ordinary shares, at a public offering price of $12.35 per ADS pursuant to the exercise in full of the underwriters' option to purchase additional ADSs in connection with our IPO (the "Greenshoe Option"). The total gross proceeds from the offering (including the previously issued 1,622,000 ADSs) increased to approximately $23 million and the net offering proceeds to us, after deducting underwriting discounts and commissions and other offering expenses, increased to approximately $21.4 million. As a result of the IPO and the underwrtiers' exercise of the Greenshoe Option, 14,574,780 shares were issued to BVF, 7,287,480 shares were issued to Apeiron, and 109,311,660 shares were issued to Apeiron Presight Capital Fund II, L.P. ("Presight"), an affiliate of Apeiron, at A$0.09645 per share.

As of June 30, 2022, we raised an aggregate of A$59.8 million in aggregate across the above fundraising activities.

The following table sets forth the aggregate number of securities held by Apeiron and BVF based on the Company's records as of October 1, 2022. Apeiron and BVF may from time to time purchase and sell shares in open market transactions on the ASX.

| 5% or Greater Shareholders(1) | Ordinary Shares | Warrants |
|---|---|---|
| Apeiron Investment Group Ltd.(2) | 260,550,387 | 142,000,000 |
| BVF Partners L.P. and its affiliates(3) | 170,089,885 | 0 |

(1) Additional details regarding these shareholders and their equity holdings are provided in this prospectus under the caption "Principal Shareholders."
(2) Based on the Company's records as of October 1, 2022.
(3) Based on the Company's records as of October 1, 2022.

**Board Nomination Rights**

Some of our directors are associated with our principal shareholders as indicated in the table below:

| Director | Principal Shareholder |
|---|---|
| Aaron Weaver | Apeiron Investment Group Ltd. |
| Miles Davies | Apeiron Investment Group Ltd. |

Under the Apeiron Subscription Agreement, on and from completion of the First Placement, Apeiron may from time to time nominate one person ("First Apeiron Nominee") to be appointed as a director of our board of directors (the "Board"). Where Apeiron has nominated the First Apeiron Nominee, the Board must resolve to appoint the First Apeiron Nominee as a director as well as supporting the nomination and reelection or appointment of the First Apeiron Nominee at our first general meeting following such appointment. We appointed Aaron Weaver to be the First Apeiron Nominee in July 2020 and his appointment was confirmed by our shareholders at the general meeting in August 2020.

Under the Apeiron Subscription Agreement, if a First Apeiron Nominee fails to be re-elected or appointed as a director at the Meeting or is otherwise removed by our board of directors, Apeiron may repeat the process set out above until there is a First Apeiron Nominee appointed to the board of directors. If Apeiron (and any

subscribers it procures) fails to continue to hold a beneficial interest in at least 10% of the Shares, Apeiron's right to have a First Apeiron Nominee on the board of directors shall cease, and if the First Apeiron Nominee is a director, Apeiron must procure that they retire immediately. We have entered into a protocol with Apeiron and the First Apeiron Nominee which sets out principles governing the provision of confidential information to the First Apeiron Nominee, and certain other customary matters for nominee director appointments ("Nominee Protocols").

Under the Apeiron Subscription Agreement, on and from completion of the Second Placement, Apeiron may from time to time nominate a further person ("Second Apeiron Nominee") to be appointed as a director of our board of directors. The Second Apeiron Nominee is to be nominated and appointed to the Board in the same manner as the First Apeiron Nominee as described above. If Apeiron (and any subscribers it procures) ceases to hold to a beneficial interest in at least: (1) 17.5% of the ordinary shares after the completion of the Second Placement until the date set out in (2) below; and (2) 20% of the ordinary shares on and from the date that is 15 months and 40 business days the date of the Meeting, then Apeiron's right to have the Second Apeiron Nominee on the board of directors will cease and Apeiron must procure that any Second Apeiron Nominee on the Board retires immediately. In July 2021, we appointed Miles Davies as the Second Apeiron Nominee who replaces Dr. Srinivas Rao who previously served as the Second Apeiron Nominee.

Under the terms of the BVF Placement Agreement, BVF may from time to time nominate one person to be to be appointed as a director our Board ("BVF Nominee"). Where BVF has nominated the BVF Nominee, the Board must resolve to appoint the BVF Nominee as a director as well as supporting the nomination and reelection or appointment of the BVF Nominee at our first general meeting following such appointment. We appointed Mr. Mitchell Kaye to be the BVF Nominee in November 2018 and his appointment was confirmed by our shareholders at the general meeting in November 2019.

Under the Placement Agreement, if a BVF Nominee fails to be re-elected or appointed as a director at general meeting or is otherwise removed by our Board, BVF may repeat the process set out above until there is a BVF Nominee appointed to the Board. If BVF (and any subscribers it procures) fails to continue to hold a beneficial interest in at least 15% of the Shares, BVF's right to have a BVF Nominee on the Board shall cease, and if the BVF Nominee is a director, BVF must procure that they retire immediately. We have entered into a protocol with BVF and the BVF Nominee which sets out principles governing the provision of confidential information to the BVF Nominee, and certain other customary matters for nominee director appointments. As of December 31, 2021, BVF failed to continue to hold a beneficial interest in at least 15% of the Shares, and BVF's right to have Mr. Mitchell Kaye on the Board ceased. Accordingly, Mr. Mitchell Kaye resigned as a director effective December 31, 2021.

**Director and Senior Management Compensation**

See "Management—Remuneration" for information regarding compensation of our senior management and directors.

**Indemnification Agreements**

Our Constitution provides that, except to the extent prohibited by law (including under the Corporations Act) and, to the extent that a director or an officer is not otherwise indemnified by us pursuant to any director and officer liability insurance policy, we will indemnify every person who is or has been a director or an officer against any liability incurred by that person as a director or an officer, unless the liability arises out of conduct on the part of the person which involves a lack of good faith or is contrary to our express instructions. To the extent that the person is not indemnified by us pursuant to any director and officer liability insurance policy, we will indemnify that person against any liability for costs and expenses incurred by the person in their capacity as director or officer in defending any legal proceedings in which judgment is given in favor of the person, or in which they were acquitted, or in connection with an application in relation to such a proceeding in which the court grants relief.

While we have obtained insurance for our directors and executive officers, we have not entered into any Deeds of Indemnity, Insurance and Access, or Indemnity Deeds, with our directors or officers.

## Principal Shareholders

The following table sets forth information known to us with respect to the beneficial ownership of our ordinary shares as of October 1, 2022, and as adjusted to reflect the sale of ADSs in this offering, by

- each of our named executive officers;
- each of our directors;
- all of our executive officers and directors as a group; and
- each person or group of affiliated persons known by us to beneficially own more than 5% of our ordinary shares.

The number of shares beneficially owned by each shareholder is determined under rules issued by the SEC. Under these rules, beneficial ownership includes any shares as to which a person has sole or shared voting power or investment power. Applicable percentage ownership is based on 1,353,350,744 ordinary shares outstanding on October 1, 2022. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, ordinary shares subject to options, warrants or other rights held by such person that are currently exercisable or will become exercisable within 60 days of October 1, 2022, 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 Bionomics Limited, 200 Greenhill Road, Eastwood SA, 5063, Australia. 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.

| | Shares Beneficially Owned | |
|---|---|---|
| **Name of Beneficial Owner** | **Number** | **Percentage** |
| ***5% or Greater Shareholders*** | | |
| BVF Partners L.P.(1) | 170,089,885 | 12.57% |
| Apeiron Investment Group Ltd(2) | 402,550,387 | 26.92% |
| ***Named Executive Officers and Directors*** | | |
| Errol De Souza, Ph.D.(3) | 30,318,168 | 2.19% |
| Adrian Hinton | 70,000 | * |
| Liz Doolin(4) | 1,127,629 | * |
| Connor Bernstein | 0 | * |
| Miles Davies | 269,984 | * |
| Alan Fisher(5) | 600,000 | * |
| Jane Ryan, Ph.D.(6) | 200,000 | * |
| Aaron Weaver | 0 | * |
| David Wilson(7) | 751,939 | * |
| All executive officers and directors as a group (9 persons) | 33,337,720 | 2.41% |

* Less than 1%.

(1) Includes (i) 77,527,212 shares held by Biotechnology Fund, L.P., (ii) 72,518,782 shares held by Biotechnology Value Fund II, L.P., (iii) 10,134,688 shares held by Biotechnology Value Trading Fund OS, L.P., (iv) 1,382,160 shares held by Investment 10, L.L.C. and (v) 8,527,043 shares held by MSI BVF SPV L.L.C. BVF Inc. as the General Partner of BVF Partners LP and Mark Lampert as a director and officer of BVF Inc., share voting and investment power over the shares beneficially owned by Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., Biotechnology Value Trading Fund OS, L.P., Investment 10, L.L.C. and MSI BVF SPV L.L.C. Each of BVF I GP LLC, BVF II GP LLC, BVF GP Holdings, LLC, BVF Partners OS Ltd, BVF Partners LP, BVF Inc and Mark Lampert disclaims beneficial ownership of the shares beneficially owned by Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., Biotechnology Value Trading Fund OS, L.P., Investment 10, L.L.C. and MSI BVF SPV L.L.C.

(2) Includes (i) 108,522 ADSs (representing 19,539,360 shares), 131,699,367 shares and 142,000,000 warrants held by Apeiron Investment Group Ltd. and (ii) 607,287 ADSs (representing 109,311,660 shares) held by Apeiron Presight Capital Fund II, L.P. Apeiron Investment Group Ltd. is owned and controlled by Christian Angermayer. Mr. Angermayer may be deemed to have beneficial ownership over the shares held by Apeiron Investment Group Ltd. Apeiron Investment Group Ltd. and Fabian Hansen are the managing members of Presight Management, which is the general partner of Apeiron Presight Capital Fund II, L.P. As a result, each of Apeiron Investment Group Ltd., Mr. Hansen and Presight Capital Management I, L.L.C. may be deemed to share beneficial ownership of the securities held by Apeiron Presight Capital Fund II, L.P.

(3) Includes (i) 366,698 shares and (ii) 26,125,422 shares that Dr. De Souza has the right to acquire pursuant to options that are exercisable as of November 30, 2022 or will become exercisable within 60 days of such date.

(4) Includes (i) 127,629 shares and (ii) 1,000,000 shares that Ms. Doolin has the right to acquire pursuant to options that are exercisable as of November 30, 2022 or will become exercisable within 60 days of such date.

(5) Includes 500,000 shares that Mr. Fisher has the right to acquire pursuant to options that are exercisable as of November 30, 2022 or will become exercisable within 60 days of such date.

(6) Includes 200,000 shares that Dr. Ryan has the right to acquire pursuant to options that are exercisable as of November 30, 2022 or will become exercisable within 60 days of such date.

(7) Includes (i) 251,939 shares and (ii) 500,000 shares that Mr. Wilson has the right to acquire pursuant to options that are exercisable as of November 30, 2022 or will become exercisable within 60 days of such date.

## Description of Share Capital

### General

The following description of our ordinary shares is only a summary. We encourage you to read our Constitution which was adopted at our Annual General Meeting held on December 2, 2021, and which is included as an exhibit to the registration statement of which this prospectus forms a part.

We are an Australian public company limited by shares registered under the Corporations Act by the Australian Securities and Investments Commission ("ASIC"). Our corporate affairs are principally governed by our Constitution, the Corporations Act and the ASX Listing Rules. Our ordinary shares trade on the ASX, and we are applying to list the ADSs on the Nasdaq Global Market.

The Australian law applicable to our Constitution is not significantly different from a U.S. company's charter documents except we do not have a limit on our authorized share capital and our shares have no par value because the concept of par value is not recognized under Australian law. Further differences are discussed under "—Our Constitution."

Subject to restrictions on the issue of securities in our Constitution, the Corporations Act and the ASX Listing Rules and any other applicable law, we may at any time issue shares and grant options or warrants on any terms, with the rights and restrictions and for the consideration that our board of directors determine.

The rights and restrictions attaching to ordinary shares are derived through a combination of our Constitution, the common law applicable in Australia, the ASX Listing Rules, the Corporations Act and other applicable law. A general summary of some of the rights and restrictions attaching to our ordinary shares are summarized below. Each ordinary shareholder is entitled to receive notice of, and to be present, vote and speak at, general meetings.

### Changes to Our Share Capital

As of June 30, 2022, we had (i) 1,353,350,744 fully paid ordinary shares issued on the ASX, of which 335,754,000 fully paid ordinary shares were issued in connection with our US IPO, (ii) 79,056,617 ordinary shares issuable upon exercise of outstanding options at a weighted average exercise price of A$0.164 ($0.11) per share, of which options to purchase 31,065,275 ordinary shares were vested at a weighted average exercise price of A$0.14 ($0.04) per share, and (iii) 142,000,000 ordinary shares issuable upon exercise of outstanding warrants at a weighted average exercise price of A$0.06 ($0.04) per share.

During the last three years, the following changes have been made to our ordinary share capital:

During the year ended June 30, 2022, we issued the following securities:

| Date | Details | No. | Issue Price A$ | Total Value A$ |
|---|---|---|---|---|
| September 2, 2021 | Share issue—exercise of options | 2.000.000 | 0.0136 | 27,200 |
| November 11, 2021 | Share issue—exercise of warrants | 8,000,000 | 0.06 | 450,000 |
| December 12, 2021 | Share issue—US IPO | 291,960,000 | 0.0645 | 28,159,542 |
| January 6, 2022 | Share issue—IPO Greenshoe Option exercised | 43,794,000 | 0.09645 | 4,223,721 |
| **Total FY2022 Movement** | | **345,754,000** | | **32,860,463** |

During the year ended June 30, 2021, we issued the following securities:

| Date | Details | No. | Issue Price A$ | Total Value A$ |
|---|---|---|---|---|
| June 4, 2021 | Share issue—placement to institutional investors | 3,909,034 | 0.145 | 566,810 |
| April 8, 2021 | Share issue—placement to institutional investors | 17,228,346 | 0.145 | 2,498,110 |

| Date | Details | No. | Issue Price A$ | Total Value A$ |
|---|---|---|---|---|
| April 8, 2021 | Share issue—entitlement offer | 140,924,683 | 0.145 | 20,434,079 |
| March 2, 2021 | Share issue—placement to institutional investors | 110,287,131 | 0.145 | 15,991,634 |
| October 22, 2020 | Share issue—entitlement offer (retail component) | 31,973,571 | 0.04 | 1,278,943 |
| October 6, 2020 | Share issue—entitlement offer (institutional component) | 22,330,875 | 0.04 | 893,235 |
| September 21, 2020 | Share issue—placement to Apeiron and four nominees | 54,333,000 | 0.04 | 2,173,320 |
| August 28, 2020 | Share issue—issue to employees pursuant to Employee Equity Plan | 424,232 | 0.1432 | 60,750 |
| **Total FY2021 Movement** | | **381,410,872** | | **43,896,881** |

During the year ended June 30, 2020, we issued the following securities:

| Date | Details | No. | Issue Price A$ | Total Value A$ |
|---|---|---|---|---|
| June 30, 2020 | Share issue—placement to nominee of Apeiron | 81,500,000 | 0.04 | 3,260,000 |
| **Total FY2020 Movement** | | **81,500,000** | | **3,260,000** |

In addition, we issued the following ordinary shares upon exercise of options over the past three fiscal years:

- on September 1, 2021, the Company issued 2,000,000 fully paid ordinary shares as a result of 2,000,0000 share options being exercised at their exercise price of $0.0136 per share;
- no ordinary shares in the fiscal year ended June 30, 2021; and
- no ordinary shares in fiscal year ended June 30, 2020.

## Our Constitution

Our Constitution is similar in nature to the bylaws of a U.S. corporation. It does not provide for or prescribe any specific objectives or purposes of the company. Our Constitution is subject to the terms of the ASX Listing Rules and the Corporations Act. It may be amended or repealed and replaced by special resolution of shareholders, which is a resolution passed by at least 75% of the votes cast by shareholders entitled to vote on the resolution who vote at the relevant meeting, in person, by proxy, by attorney or by representative.

Under Australian law, a company has the legal capacity and powers of an individual both within and outside Australia. The material provisions of our Constitution are summarized below. This summary is not intended to be complete nor to constitute a definitive statement of the rights and liabilities of our shareholders. Our Constitution is filed as an exhibit to the registration statement of which this prospectus forms a part.

### *Interested Directors*

According to our Constitution and the Corporations Act, a director may not vote in respect of any matter in which the director has, directly or indirectly, any material personal interest, must not be counted in a quorum and must not be present at the meeting while the matter is being considered (unless the other directors, not having a material personal interest, resolve to the contrary, or if they are so entitled under a declaration or order made by ASIC in accordance with the Corporations Act). Subject to certain exceptions, each director must disclose to us particulars of: (1) any material contract in which the director is interested, including the names of the parties to the contract, particulars of the contract, and the director’s interest in the contract; and (2) any material personal interest in a matter that is being considered at a meeting of our board of directors.

Provided that a director makes disclosure as required by our Constitution and the Corporations Act, the director and any firm, body or entity in which a director has a direct or indirect interest may, in any capacity, execute or otherwise act in respect of a contract or arrangement with us notwithstanding any material personal interest and may receive and retain for his or her benefit any remuneration, profits or benefits so received as if he or she were not a director.

The Corporations Act and the ASX Listing Rules require shareholder approval of any provision of related party benefits to our directors, subject to certain exceptions.

***Directors' Compensation***

Our directors are paid remuneration for their services as directors. The maximum aggregate amount of fees that can be paid to non-executive directors is subject to approval by shareholders at a general meeting of shareholders. The aggregate fixed sum for directors' remuneration is divided among the directors in such proportion as the directors themselves agree and in accordance with our Constitution. The aggregate fixed sum remuneration for directors may not be increased except at a general meeting of shareholders and the particulars of the proposed increase are required to have been provided to shareholders in the notice convening the meeting. Fees for non-executive directors are not linked to our performance. However, to align directors' interests with shareholder interests, the directors are encouraged to hold our ordinary shares. Employees of our company who also serve as directors do not receive additional compensation for their performance of services as directors.

Pursuant to our Constitution, any non-executive director who performs services that, in the opinion of our board of directors, are outside the scope of the ordinary duties of a director may be paid extra remuneration by way of a fixed sum, which is determined by our board of directors, provided such payment does not result in the aggregate of all remuneration paid to non-executive directors exceeding the maximum sum approved at the general meeting of shareholders.

Executive directors may be paid remuneration as employees of the company and such remuneration may from time to time be fixed by our board of directors. Subject to the ASX Listing Rules, the remuneration may be by way of salary, commission, participation in profits, by the issue or allotment of shares or options over unissued shares or by all or any of these modes, but must not be by commission on, or a percentage of, operating revenue.

In addition to other remuneration provided in our Constitution, all of our directors are entitled to be paid by us for travel accommodation and other expenses properly incurred by the directors in attending general meetings, Board meetings, committee meetings or otherwise in connection with our business.

We may also pay a premium in respect of a contract insuring a person who is or has been a director against liability incurred by the person as a director, except in circumstances prohibited by the Corporations Act or other applicable laws.

In accordance with our Constitution, a director may also be paid a retirement benefit as determined by our board of directors, subject to the limits set out in the Corporations Act and the ASX Listing Rules which broadly restrict our ability to pay our officers a termination benefit in the event of a change of control of Bionomics or of our subsidiaries as well as impose requirements for shareholder approval to be obtained to pay certain retirement benefits to our officers.

***Borrowing Powers Exercisable by Directors***

Pursuant to our Constitution, the management and control of our business affairs are vested in our board of directors. Our board of directors has the power to raise or borrow money, and charge any of our property or business or any uncalled capital, and may issue debentures or give any other security for any of our debts, liabilities or obligations or of any other person, or guarantee or become liable for the payment of money or the performance of any obligation by or for any other person, in each case, in the manner and on terms it deems fit.

***Retirement of Directors***

In accordance with our Constitution and the ASX Listing Rules, at each annual general meeting, one-third of our directors (other than the Executive Chairman (who in substance fulfils the role of Managing Director)) must retire from office and their positions be open to election. The retiring directors are eligible for re-election to our board of directors. If the number of directors subject to retirement is not equal to three, or a multiple of three, then the number nearest to, but not exceeding, one-third must retire from office. The directors who retire in this manner are required to be the directors longest in office since last being elected (and in the case where more than one director was elected on the same day, they may agree amongst themselves or determine by lot which of them is subject to retirement). In addition, each director (other than the Executive Chairman) must retire at the later of the third annual general meeting after his or her election or three years after such director was last appointed.

***Rights and Restrictions on Classes of Shares***

The rights attaching to our ordinary shares are detailed in our Constitution. Our Constitution provides that our directors may issue shares with preferred or other special rights, whether in relation to dividends, voting, return of share capital, or otherwise as our board of directors may determine. Subject to any approval which is required from our shareholders under the Corporations Act and the ASX Listing Rules (see "—Exemptions from Certain Nasdaq Corporate Governance Rules" and "—Change of Control"), and any rights and restrictions attached to a class of shares, we may issue further shares on such terms and conditions as our board of directors resolve. Currently, our outstanding share capital consists of only one class of ordinary shares.

***Dividend Rights***

Our board of directors may from time to time determine to pay dividends to shareholders. All dividends unclaimed for 11 months after having been declared may be invested or otherwise made use of by our board of directors for our benefit until claimed or otherwise disposed of in accordance with our Constitution and any applicable laws.

***Voting Rights***

Under our Constitution, and subject to any voting exclusions imposed under the ASX Listing Rules (which typically exclude parties from voting on resolutions proposed for the purposes of the ASX Listing Rules in which they have an interest), the rights and restrictions attaching to a class of shares, each shareholder has one vote on a show of hands at a meeting of the shareholders unless a poll is demanded under the Constitution or the Corporations Act. On a poll vote, each shareholder shall have one vote for each fully paid share and a fractional vote for each share held by that shareholder that is not fully paid, such fraction being equivalent to the proportion of the amount that has been paid to such date on that share. Shareholders may vote in person or by proxy, attorney or representative. The Corporations Act does not provide for shareholders of a public company to approve corporate matters by written consent. Our Constitution does not provide for cumulative voting.

Note that ADS holders may not directly vote at a meeting of the shareholders but may instruct the depositary to vote the number of deposited ordinary shares their ADSs represent.

***Right to Share in Our Profits***

Pursuant to our Constitution, our shareholders are entitled to participate in our profits only by payment of dividends. Our board of directors may from time to time determine to pay dividends to the shareholders; however, no dividend is payable except in accordance with the thresholds set out in the Corporations Act.

***Rights to Share in the Surplus in the Event of Liquidation***

Our Constitution provides for the right of shareholders to participate equally in a surplus in the event of our liquidation, subject to the rights attaching to a class of shares and any amounts unpaid on the share.

***No Redemption Provision for Ordinary Shares***

There are no redemption provisions in our Constitution in relation to ordinary shares. Under our Constitution, any preferred shares may be issued on the terms that they are, or may at our option be, liable to be redeemed.

***Variation or Cancellation of Share Rights***

Subject to the terms of issue of shares of that class, the rights attached to shares in a class of shares may only be varied or cancelled with either:

- a special resolution passed at a separate meeting of the members holding shares in that class; or
- the written consent of members with at least 75% of the issued shares in that class.

***Directors May Make Calls***

Our Constitution provides that subject to the terms on which partly paid shares have been issued directors may make calls on a shareholder for amounts unpaid on those shares held by that shareholder, other than monies payable at fixed times under the conditions of allotment. Shares represented by the ADSs issued in this offering will be fully paid and will not be subject to calls by directors.

**General Meetings of Shareholders**

General meetings of shareholders may be called by our board of directors. Except as permitted under the Corporations Act, shareholders may not convene a meeting. The Corporations Act requires the directors to call and arrange to hold a general meeting on the request of shareholders with at least 5% of the votes that may be cast at a general meeting. The Corporations Act also allows shareholders with at least 5% of the votes that may be cast at a general meeting to convene a general meeting. Notice of the proposed meeting of our shareholders is required at least 28 days prior to such meeting under the Corporations Act. We must hold an annual general meeting at least once in each calendar year, and within five months after the end of each fiscal year.

**Foreign Ownership Regulation**

There are no limitations on the rights to own securities imposed by our Constitution. However, acquisitions and proposed acquisitions of securities in Australian companies may be subject to review and approval by the Australian Federal Treasurer under the Australian Foreign Acquisitions and Takeovers Act 1975 (as amended) (the "FATA"), which generally applies to acquisitions or proposed acquisitions:

- by a foreign person (as defined in the FATA) or associated foreign persons that would result in such persons having an interest in 20% or more of the issued shares of, or control of 20% or more of the voting power or potential voting power in, an Australian company; and
- by foreign persons (and their associates) that would result in such foreign persons (and their associates) having an interest in 40% or more of the issued shares of, or control of 40% or more of the voting power or potential voting power in, an Australian company, where the Australian company is valued above the monetary thresholds prescribed by FATA.

However, no such review or approval under the FATA is required if the foreign acquirer is a private U.S. entity (but not including overseas subsidiaries of U.S. entities) and the value of the Australian company is less than A$1,216 million.

The Australian Federal Treasurer may prevent a proposed acquisition in the above categories or impose conditions on such acquisition if the Treasurer is satisfied that the acquisition would be contrary to the national interest. If a foreign person acquires shares or an interest in shares in an Australian company that is subject to review and approval under FATA, but such approval is not obtained, the Australian Federal Treasurer may order the divestiture of such person's shares or interest in shares in that Australian company.

In addition, under FATA, all foreign government investors must notify the Australian Government and get prior approval before making a direct investment in Australia, regardless of the value of the investment. What constitutes a foreign government investor is defined broadly in FATA.

**Ownership Threshold**

There are no provisions in our Constitution that require a shareholder to disclose ownership above a certain threshold. The Corporations Act, however, requires a shareholder to notify us and the ASX once it, together with its associates, acquires an interest of 5% or more in our ordinary shares (or voting power (as defined in the Corporations Act) of 5% or more of the votes in our ordinary shares), at which point the shareholder will be considered to be a "substantial" shareholder. Further, once a shareholder (alone or together with its associates) owns an interest of 5% or more in us, such shareholder must notify us and the ASX of any increase or decrease of 1% or more in its holding of our ordinary shares, and must also notify us and the ASX on its ceasing to be a "substantial" shareholder. In most cases, such notice must be given to us and the ASX within two business days after the relevant shareholder becomes aware of the information. Upon becoming a U.S. public company, our shareholders will also be subject to disclosure requirements under U.S. securities laws.

**No Shareholder Approval of Offering**

Under the ASX Listing Rules, a company must not, subject to specified exceptions, without the approval of its shareholders, issue or agree to issue, during any 12 month period, any equity securities, or other securities with rights to convert into equity, if the number of those securities exceeds 15% of the number of shares on issue at the commencement of that 12 month period ("Placement Capacity"). If approval of shareholders is obtained at an eligible company's annual general meeting then the company can issue an additional 10% of equity securities over a 12-month period after that annual general meeting or until the next annual general meeting, whichever is first to occur ("Additional Placement Capacity"). The Placement Capacity and Additional Placement Capacity are together referred to as the "Combined Placement Capacity."

At our Annual General Meeting of shareholders on December 2, 2021, we sought and received the approval of our shareholders to obtain Additional Placement Capacity. We will also be proposing a resolution at our Annual General Meeting to be held on November 16, 2022 to seek to renew this Additional Placement Capacity.

New shares to be issued in connection with this offering do not fall within any of the specified exceptions and we will utilize our existing Placement Capacity or, if we have Additional Placement Capacity that is current at the time of issue, our existing Combined Placement Capacity. Our existing Placement Capacity is shares and our existing Additional Placement Capacity is shares. Accordingly, if we issue ADS in connection with this offering (each representing 180 ordinary shares) these shares will be counted towards our existing Placement Capacity or, if we have Additional Placement Capacity that is current at the time of issue, our Combined Placement Capacity which in either case will be reduced accordingly.

**Issues of Shares and Change in Capital**

Subject to our Constitution, the Corporations Act, the ASX Listing Rules and any other applicable law, we may at any time issue shares and grant options or warrants on any terms, with preferred or other special rights and restrictions and for the consideration and other terms that the directors determine.

Subject to the requirements of our Constitution, the Corporations Act, the ASX Listing Rules and any other applicable law, including relevant shareholder approvals, we may consolidate or divide our share capital into a larger or smaller number by resolution, reduce our share capital (provided that the reduction is fair and reasonable to our shareholders as a whole and does not materially prejudice our ability to pay creditors) or buy back our ordinary shares whether under an equal access buy-back or on a selective basis.

The Corporations Act and the ASX Listing Rules permit a company to convert its securities into a larger or smaller number by resolution passed by shareholders at a general meeting. The purpose of the Consolidation is to

implement a more appropriate capital structure, and to ensure a more appropriate share price, option exercise price and warrant exercise price for our investors.

**Change of Control**

Takeovers of listed Australian public companies are regulated by the Corporations Act, which prohibits the acquisition of a "relevant interest" in issued voting shares in a listed company if the acquisition will lead to that person's or someone else's voting power (as defined in the Corporations Act) increasing from 20% or below to more than 20% or increasing from a starting point that is above 20% and below 90%, subject to a range of exceptions.

Generally, a person will have a relevant interest in securities if the person:

- is the holder of the securities;
- has power to exercise, or control the exercise of, a right to vote attached to the securities; or
- has the power to dispose of, or control the exercise of a power to dispose of, the securities, including any indirect or direct power or control.

If, at a particular time, a person has a relevant interest in issued securities and the person:

- has entered or enters into an agreement with another person with respect to the securities; or
- has given or gives another person an enforceable right, or has been or is given an enforceable right by another person, in relation to the securities (whether the right is enforceable presently or in the future and whether or not on the fulfillment of a condition); or
- has granted or grants an option to, or has been or is granted an option by, another person with respect to the securities; and
- the other person would have a relevant interest in the securities if the agreement were performed, the right enforced or the option exercised,

then the other person is deemed to already have a relevant interest in the securities.

There are a number of exceptions to the above prohibition on acquiring a relevant interest in issued voting shares above 20%. In general terms, some of the more significant exceptions include:

- when the acquisition results from the acceptance of an offer under a takeover bid that complies with the Corporations Act;
- when the acquisition is conducted on market by or on behalf of the bidder under a takeover bid that complies with the Corporations Act, the acquisition occurs during the bid period, the bid is for all the voting shares in a bid class and the bid is unconditional or only conditioned on prescribed matters set out in the Corporations Act;
- when shareholders (other than the persons making the acquisitions and their associates) approve the acquisition by resolution passed at general meeting;
- an acquisition by a person if, throughout the six months before the acquisition, that person or any other relevant person has had voting power of at least 19% and, as a result of the acquisition, none of the relevant persons would have voting power more than three percentage points higher than they had six months before the acquisition;
- when the acquisition results from the issue of securities under a rights issue (subject, in certain cases, to compliance with conditions);
- when the acquisition results from the issue of securities under dividend reinvestment schemes;

- when the acquisition results from the issue of securities to an underwriter or sub-underwriter under underwriting arrangements;
- when the acquisition results from the issue of securities through a will or through operation of law;
- an acquisition that arises through the acquisition of a relevant interest in another listed company which is listed on a prescribed financial market or a financial market approved by ASIC;
- an acquisition arising from an auction of forfeited shares conducted on-market; or
- an acquisition arising through a compromise, arrangement, liquidation or buy-back.

Breaches of the takeovers provisions of the Corporations Act are criminal offenses. Australian courts and the Australian Takeovers Panel have a wide range of powers relating to breaches of takeover provisions, including the ability to make orders canceling contracts, freezing transfers of, and rights attached to, securities, and forcing a party to dispose of securities. There are certain defenses to breaches of the takeover provisions provided in the Corporations Act.

**Access to and Inspection of Documents**

Inspection of our records is governed by the Corporations Act. Any member of the public has the right to inspect or obtain copies of our registers on the payment of a prescribed fee (provided that the purpose to obtain copies is not a "prescribed purpose" for the purposes of the Corporations Act). Shareholders are not required to pay a fee for inspection of our registers or minute books of the meetings of shareholders. Other corporate records, including minutes of directors' meetings, financial records and other documents, are not open for inspection by shareholders. Where a shareholder is acting in good faith and an inspection is deemed to be made for a proper purpose, a shareholder may apply to the court to make an order for inspection of our books.

**Exemptions from Certain Nasdaq Corporate Governance Rules**

The Nasdaq Listing Rules allow for a foreign private issuer, such as Bionomics, to follow its home country practices in lieu of certain of the Nasdaq's corporate governance standards. In connection with our Nasdaq Listing Application, we expect to rely on exemptions from certain corporate governance standards that are contrary to the laws, rules, regulations or generally accepted business practices in the United States. These exemptions being sought are described below:

- We expect to rely on an exemption from the independence requirements for a majority of our board of directors as prescribed by Nasdaq Listing Rules. The ASX Listing Rules do not require us to have a majority of independent directors although ASX Corporate Governance Principles and Recommendations do recommend a majority of independent directors. During the fiscal year ended June 30, 2022, three of our six directors were "independent" as defined in the ASX Corporate Governance Principles and Recommendations, which definition differs from Nasdaq's definition. Accordingly, because Australian law and generally accepted business practices in Australia regarding director independence differ to the independence requirements under Nasdaq Listing Rules, we seek to claim this exemption.
- We expect to rely on an exemption from the requirement that our independent directors meet regularly in executive sessions under Nasdaq Listing Rules. The ASX Listing Rules and the Corporations Act do not require the independent directors of an Australian company to have such executive sessions and, accordingly, we seek to claim this exemption.
- We expect to rely on an exemption from the quorum requirements applicable to meetings of shareholders under Nasdaq Listing Rules. In compliance with Australian law, our Constitution provides that two shareholders present and entitled to vote, whether present in person or by proxy, attorney or a representative, shall constitute a quorum for a general meeting. Nasdaq Listing Rules require that an issuer provide for a quorum as specified in its bylaws for any meeting of the holders of ordinary shares,

which quorum may not be less than 33-1/3% of the outstanding shares of an issuer's voting ordinary shares. Accordingly, because applicable Australian law and rules governing quorums at shareholder meetings differ from Nasdaq's quorum requirements, we seek to claim this exemption.

- We expect to rely on an exemption from the requirement prescribed by Nasdaq Listing Rules that issuers obtain shareholder approval prior to the issuance of securities in connection with certain acquisitions, private placements of securities, or the establishment or amendment of certain equity option, purchase or other compensation plans. Applicable Australian law and the ASX Listing Rules differ from Nasdaq requirements, with the ASX Listing Rules providing generally for prior shareholder approval in numerous circumstances, including (i) issuance of equity securities exceeding 15% of our issued share capital in any 12-month period (but, in determining the 15% limit, securities issued under an exception to the rule or with shareholder approval are not counted), (ii) issuance of equity securities to related parties (as defined in the ASX Listing Rules) and (iii) issuances of securities to directors or their associates under an employee incentive plan. Due to differences between Australian law and rules and the Nasdaq shareholder approval requirements, we seek to claim this exemption.

## Description of American Depositary Shares

Citibank, N.A. has agreed to act as the depositary bank for the American Depositary Shares. Citibank's depositary offices are located at 388 Greenwich Street, New York, New York 10013. American Depositary Shares are frequently referred to as "ADSs" and represent ownership interests in securities that are on deposit with the depositary bank. ADSs may be represented by certificates that are commonly known as "American Depositary Receipts" or "ADRs." The depositary bank typically appoints a custodian to safekeep the securities on deposit. In this case, the custodian is Citicorp Nominees Pty Limited**,** located at Level 15, 120 Collins Street, Melbourne VIC 3000**.**

We have appointed Citibank as depositary bank pursuant to a deposit agreement. A copy of the deposit agreement is on file with the SEC under cover of a Registration Statement on Form F-6. You may obtain a copy of the deposit agreement from the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 and from the SEC's website (www.sec.gov).

We are providing you with a summary description of the material terms of the ADSs and of your material rights as an owner of ADSs. Please remember that summaries by their nature lack the precision of the information summarized and that the rights and obligations of an owner of ADSs will be determined by reference to the terms of the deposit agreement and not by this summary. We urge you to review the deposit agreement in its entirety. The portions of this summary description that are italicized describe matters that may be relevant to the ownership of ADSs but that may not be contained in the deposit agreement.

Each ADS represents the right to receive, and to exercise the beneficial ownership interests in, 180 ordinary shares that are on deposit with the depositary bank and/or custodian. An ADS also represents the right to receive, and to exercise the beneficial interests in, any other property received by the depositary bank or the custodian on behalf of the owner of the ADS but that has not been distributed to the owners of ADSs because of legal restrictions or practical considerations. We and the depositary bank may agree to change the ADS-to-ordinary shares ratio by amending the deposit agreement. This amendment may give rise to, or change, the depositary fees payable by ADS owners. The custodian, the depositary bank and their respective nominees will hold all deposited property for the benefit of the holders and beneficial owners of ADSs. The deposited property does not constitute the proprietary assets of the depositary bank, the custodian or their nominees. Beneficial ownership in the deposited property will under the terms of the deposit agreement be vested in the beneficial owners of the ADSs. The depositary bank, the custodian and their respective nominees will be the record holders of the deposited property represented by the ADSs for the benefit of the holders and beneficial owners of the corresponding ADSs. A beneficial owner of ADSs may or may not be the holder of ADSs. Beneficial owners of ADSs will be able to receive, and to exercise beneficial ownership interests in, the deposited property only through the registered holders of the ADSs, the registered holders of the ADSs (on behalf of the applicable ADS owners) only through the depositary bank, and the depositary bank (on behalf of the owners of the corresponding ADSs) directly, or indirectly, through the custodian or their respective nominees, in each case upon the terms of the deposit agreement.

If you become an owner of ADSs, you will become a party to the deposit agreement and therefore will be bound to its terms and to the terms of any ADR that represents your ADSs. The deposit agreement and the ADR specify our rights and obligations as well as your rights and obligations as an owner of ADSs and those of the depositary bank. As an ADS holder you appoint the depositary bank to act on your behalf in certain circumstances. The deposit agreement and the ADRs are governed by New York law. However, our obligations to the holders of ordinary shares will continue to be governed by the laws of Australia, which may be different from the laws in the United States.

In addition, applicable laws and regulations may require you to satisfy reporting requirements and obtain regulatory approvals in certain circumstances. You are solely responsible for complying with such reporting requirements and obtaining such approvals. Neither the depositary bank, the custodian, us or any of their or our

respective agents or affiliates shall be required to take any actions whatsoever on your behalf to satisfy such reporting requirements or obtain such regulatory approvals under applicable laws and regulations.

*As an owner of ADSs, we will not treat you as one of our shareholders and you will not have direct shareholder rights. The depositary bank will hold on your behalf the shareholder rights attached to the ordinary shares underlying your ADSs. As an owner of ADSs you will be able to exercise the shareholders rights for the ordinary shares represented by your ADSs through the depositary bank only to the extent contemplated in the deposit agreement. To exercise any shareholder rights not contemplated in the deposit agreement you will, as an ADS owner, need to arrange for the cancellation of your ADSs and become a direct shareholder.*

The manner in which you own the ADSs (e.g., in a brokerage account vs. as registered holder, or as holder of certificated vs. uncertificated ADSs) may affect your rights and obligations, and the manner in which, and extent to which, the depositary bank's services are made available to you. As an owner of ADSs, you may hold your ADSs either by means of an ADR registered in your name, through a brokerage or safekeeping account, or through an account established by the depositary bank in your name reflecting the registration of uncertificated ADSs directly on the books of the depositary bank (commonly referred to as the "direct registration system" or "DRS"). The direct registration system reflects the uncertificated (book-entry) registration of ownership of ADSs by the depositary bank. Under the direct registration system, ownership of ADSs is evidenced by periodic statements issued by the depositary bank to the holders of the ADSs. The direct registration system includes automated transfers between the depositary bank and The Depository Trust Company ("DTC"), the central book-entry clearing and settlement system for equity securities in the United States. If you decide to hold your ADSs through your brokerage or safekeeping account, you must rely on the procedures of your broker or bank to assert your rights as ADS owner. Banks and brokers typically hold securities such as the ADSs through clearing and settlement systems such as DTC. The procedures of such clearing and settlement systems may limit your ability to exercise your rights as an owner of ADSs. Please consult with your broker or bank if you have any questions concerning these limitations and procedures. All ADSs held through DTC will be registered in the name of a nominee of DTC. This summary description assumes you have opted to own the ADSs directly by means of an ADS registered in your name and, as such, we will refer to you as the "holder." When we refer to "you," we assume the reader owns ADSs and will own ADSs at the relevant time.

The registration of the ordinary shares in the name of the depositary bank or the custodian shall, to the maximum extent permitted by applicable law, vest in the depositary bank or the custodian the record ownership in the applicable ordinary shares with the beneficial ownership rights and interests in such ordinary shares being at all times vested with the beneficial owners of the ADSs representing the ordinary shares. The depositary bank or the custodian shall at all times be entitled to exercise the beneficial ownership rights in all deposited property, in each case only on behalf of the holders and beneficial owners of the ADSs representing the deposited property.

**Dividends and Distributions**

As a holder of ADSs, you generally have the right to receive the distributions we make on the securities deposited with the custodian. Your receipt of these distributions may be limited, however, by practical considerations and legal limitations. Holders of ADSs will receive such distributions under the terms of the deposit agreement in proportion to the number of ADSs held as of the specified record date, after deduction of the applicable fees, taxes and expenses.

**Distributions of Cash**

Whenever we make a cash distribution for the securities on deposit with the custodian, we will deposit the funds with the custodian. Upon receipt of confirmation of the deposit of the requisite funds, the depositary bank will arrange for the funds received in a currency other than U.S. dollars to be converted into U.S. dollars and for the distribution of the U.S. dollars to the holders, subject to the laws and regulations of Australia.

The conversion into U.S. dollars will take place only if practicable and if the U.S. dollars are transferable to the United States. The depositary bank will apply the same method for distributing the proceeds of the sale of any property (such as undistributed rights) held by the custodian in respect of securities on deposit.

The distribution of cash will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. The depositary bank will hold any cash amounts it is unable to distribute in a non-interest bearing account for the benefit of the applicable holders and beneficial owners of ADSs until the distribution can be effected or the funds that the depositary bank holds must be escheated as unclaimed property in accordance with the laws of the relevant states of the United States.

**Distributions of Ordinary Shares**

Whenever we make a free distribution of ordinary shares for the securities on deposit with the custodian, we will deposit the applicable number of ordinary shares with the custodian. Upon receipt of confirmation of such deposit, the depositary bank will either distribute to holders new ADSs representing the ordinary shares deposited or modify the ADS-to-ordinary shares ratio, in which case each ADS you hold will represent rights and interests in the additional ordinary shares so deposited. Only whole new ADSs will be distributed. Fractional entitlements will be sold and the proceeds of such sale will be distributed as in the case of a cash distribution.

The distribution of new ADSs or the modification of the ADS-to-ordinary shares ratio upon a distribution of ordinary shares will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes or governmental charges, the depositary bank may sell all or a portion of the new ordinary shares so distributed.

No such distribution of new ADSs will be made if it would violate a law (*e.g.*, the U.S. securities laws) or if it is not operationally practicable. If the depositary bank does not distribute new ADSs as described above, it may sell the ordinary shares received upon the terms described in the deposit agreement and will distribute the proceeds of the sale as in the case of a distribution of cash.

**Distributions of Rights**

Whenever we intend to distribute rights to subscribe for additional ordinary shares, we will give prior notice to the depositary bank and we will assist the depositary bank in determining whether it is lawful and reasonably practicable to distribute rights to subscribe for additional ADSs to holders.

The depositary bank will establish procedures to distribute rights to subscribe for additional ADSs to holders and to enable such holders to exercise such rights if we request such rights be made available to holders of ADSs, it is lawful and reasonably practicable to make the rights available to holders of ADSs, and if we provide all of the documentation contemplated in the deposit agreement (such as opinions to address the lawfulness of the transaction). You may have to pay fees, expenses, taxes and other governmental charges to subscribe for the new ADSs upon the exercise of your rights. The depositary bank is not obligated to establish procedures to facilitate the distribution and exercise by holders of rights to subscribe for new ordinary shares other than in the form of ADSs.

The depositary bank will *not* distribute the rights to you if:

- We do not timely request that the rights be distributed to you or we request that the rights not be distributed to you; or
- We fail to deliver satisfactory documents to the depositary bank; or
- It is not reasonably practicable to distribute the rights.

The depositary bank will sell the rights that are not exercised or not distributed if such sale is lawful and reasonably practicable. The proceeds of such sale will be distributed to holders as in the case of a cash distribution. If the depositary bank is unable to sell the rights, it will allow the rights to lapse.

**Elective Distributions**

Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary bank and will indicate whether we wish the elective distribution to be made available to you. In such case, we will assist the depositary bank in determining whether such distribution is lawful and reasonably practicable.

The depositary bank will make the election available to you only if we request and it is reasonably practicable and if we have provided all of the documentation contemplated in the deposit agreement. In such case, the depositary bank will establish procedures to enable you to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement.

If the election is not made available to you, you will receive either cash or additional ADSs, depending on what a shareholder in Australia would receive upon failing to make an election, as more fully described in the deposit agreement.

**Other Distributions**

Whenever we intend to distribute property other than cash, ordinary shares or rights to subscribe for additional ordinary shares, we will notify the depositary bank in advance and will indicate whether we wish such distribution to be made to you. If so, we will assist the depositary bank in determining whether such distribution to holders is lawful and reasonably practicable.

If it is reasonably practicable to distribute such property to you and if we request such rights be made available to you and provide to the depositary bank all of the documentation contemplated in the deposit agreement, the depositary bank will distribute the property to the holders in a manner it deems practicable.

The distribution will be made net of fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes and governmental charges, the depositary bank may sell all or a portion of the property received.

The depositary bank will *not* distribute the property to you and will sell the property if:

- We do not request that the property be distributed to you or if we request that the property not be distributed to you; or
- We do not deliver satisfactory documents to the depositary bank; or
- The depositary bank determines that all or a portion of the distribution to you is not reasonably practicable.

The proceeds of such a sale will be distributed to holders as in the case of a cash distribution.

**Redemption**

Whenever we decide to redeem any of the securities on deposit with the custodian, we will notify the depositary bank in advance. If it is practicable and if we provide all of the documentation contemplated in the deposit agreement, the depositary bank will provide notice of the redemption to the holders.

The custodian will be instructed to surrender the shares being redeemed against payment of the applicable redemption price. The depositary bank will convert into U.S. dollars upon the terms of the deposit agreement the redemption funds received in a currency other than U.S. dollars and will establish procedures to enable holders to receive the net proceeds from the redemption upon surrender of their ADSs to the depositary bank. You may have to pay fees, expenses, taxes and other governmental charges upon the redemption of your ADSs. If less than all ADSs are being redeemed, the ADSs to be retired will be selected by lot or on a *pro rata* basis, as the depositary bank may determine.

**Changes Affecting Ordinary Shares**

The ordinary shares held on deposit for your ADSs may change from time to time. For example, there may be a split-up, cancellation, consolidation or any other reclassification of such ordinary shares or a recapitalization, reorganization, merger, consolidation or sale of assets of the Company.

If any such change were to occur, your ADSs would, to the extent permitted by law and the deposit agreement, represent the right to receive the property received or exchanged in respect of the ordinary shares held on deposit. The depositary bank may in such circumstances deliver new ADSs to you, amend the deposit agreement, the ADRs and the applicable Registration Statement(s) on Form F-6, call for the exchange of your existing ADSs for new ADSs and take any other actions that are appropriate to reflect as to the ADSs the change affecting the Shares. If the depositary bank may not lawfully distribute such property to you, the depositary bank may sell such property and distribute the net proceeds to you as in the case of a cash distribution.

**Issuance of ADSs upon Deposit of Ordinary Shares**

Upon completion of the offering, the ordinary shares being offered hereby will be deposited by us with the custodian. Upon receipt of confirmation of such deposit, the depositary bank will issue ADSs to the underwriters named herein.

After the closing of the offering, the depositary bank may create ADSs on your behalf if you or your broker deposit ordinary shares with the custodian and provide the certifications and documentation required by the deposit agreement. The depositary bank will deliver these ADSs to the person you indicate only after you pay any applicable issuance fees and any charges and taxes payable for the transfer of the ordinary shares to the custodian. Your ability to deposit ordinary shares and receive ADSs may be limited by U.S. and Australian legal considerations applicable at the time of deposit.

The issuance of ADSs may be delayed until the depositary bank or the custodian receives confirmation that all required approvals have been given and that the ordinary shares have been duly transferred to the custodian. The depositary bank will only issue ADSs in whole numbers.

When you make a deposit of ordinary shares, you will be responsible for transferring good and valid title to the depositary bank. As such, you will be deemed to represent and warrant that:

- The ordinary shares are validly issued, fully paid and legally obtained.
- You are duly authorized to deposit the ordinary shares.
- The ordinary shares presented for deposit are free and clear of any lien, encumbrance, security interest, charge, mortgage or adverse claim, and are not, and the ADSs issuable upon such deposit will not be, “restricted securities” (as defined in the deposit agreement).
- The ordinary shares presented for deposit have not been stripped of any rights or entitlements.

If any of the representations or warranties are incorrect in any way, we and the depositary bank may, at your cost and expense, take any and all actions necessary to correct the consequences of the misrepresentations.

**Transfer, Combination and Split Up of ADRs**

As an ADR holder, you will be entitled to transfer, combine or split up your ADRs and the ADSs evidenced thereby. For transfers of ADRs, you will have to surrender the ADRs to be transferred to the depositary bank and also must:

- ensure that the surrendered ADR is properly endorsed or otherwise in proper form for transfer;
- provide such proof of identity and genuineness of signatures as the depositary bank deems appropriate;
- provide any transfer stamps required by the State of New York or the United States; and
- pay all applicable fees, charges, expenses, taxes and other government charges payable by ADR holders pursuant to the terms of the deposit agreement, upon the transfer of ADRs.

To have your ADRs either combined or split up, you must surrender the ADRs in question to the depositary bank with your request to have them combined or split up, and you must pay all applicable fees, charges and expenses payable by ADR holders, pursuant to the terms of the deposit agreement, upon a combination or split up of ADRs.

**Withdrawal of Ordinary Shares Upon Cancellation of ADSs**

As a holder, you will be entitled to present your ADSs to the depositary bank for cancellation and then receive the corresponding number of underlying ordinary shares at the custodian's offices. Your ability to withdraw the ordinary shares held in respect of the ADSs may be limited by U.S. and Australian law considerations applicable at the time of withdrawal. In order to withdraw the ordinary shares represented by your ADSs, you will be required to pay to the depositary bank the fees for cancellation of ADSs and any charges and taxes payable upon the transfer of the ordinary shares. You assume the risk for delivery of all funds and securities upon withdrawal. Once canceled, the ADSs will not have any rights under the deposit agreement.

If you hold ADSs registered in your name, the depositary bank may ask you to provide proof of identity and genuineness of any signature and such other documents as the depositary bank may deem appropriate before it will cancel your ADSs. The withdrawal of the ordinary shares represented by your ADSs may be delayed until the depositary bank receives satisfactory evidence of compliance with all applicable laws and regulations. Please keep in mind that the depositary bank will only accept ADSs for cancellation that represent a whole number of securities on deposit.

You will have the right to withdraw the securities represented by your ADSs at any time except for:

- temporary delays that may arise because (i) the transfer books for the ordinary shares or ADSs are closed, or (ii) ordinary shares are immobilized on account of a shareholders' meeting or a payment of dividends;
- obligations to pay fees, taxes and similar charges; and/or
- restrictions imposed because of laws or regulations applicable to ADSs or the withdrawal of securities on deposit.

The deposit agreement may not be modified to impair your right to withdraw the securities represented by your ADSs except to comply with mandatory provisions of law.

**Voting Rights**

As a holder, you generally have the right under the deposit agreement to instruct the depositary bank to exercise the voting rights for the ordinary shares represented by your ADSs. The voting rights of holders of ordinary shares are described in "Description of Share Capital."

At our request, the depositary bank will distribute to you any notice of shareholders' meeting received from us together with information explaining how to instruct the depositary bank to exercise the voting rights of the securities represented by ADSs. In lieu of distributing such materials, the depositary bank may distribute to holders of ADSs instructions on how to retrieve such materials upon request.

If the depositary bank timely receives voting instructions from a holder of ADSs, it will endeavor to vote the securities (in person or by proxy) represented by the holder's ADSs as follows:

- *In the event of voting by show of hands*, the depositary bank will vote (or cause the custodian to vote) all ordinary shares held on deposit at that time in accordance with the voting instructions received from a majority of holders of ADSs who provide timely voting instructions.
- *In the event of voting by poll*, the depositary bank will vote (or cause the Custodian to vote) the ordinary shares held on deposit in accordance with the voting instructions received from the holders of ADSs.

Securities for which no voting instructions have been received will not be voted (except as set forth above in the case voting is by show of hands and as otherwise contemplated in the deposit agreement). Please note that the ability of the depositary bank to carry out voting instructions may be limited by practical and legal limitations and the terms of the securities on deposit. We cannot assure you that you will receive voting materials in time to enable you to return voting instructions to the depositary bank in a timely manner.

**Fees and Charges**

As an ADS holder, you will be required to pay the following fees under the terms of the deposit agreement:

| Service | Fees |
|---|---|
| • Issuance of ADSs (e.g., an issuance of ADS upon a deposit of ordinary shares, upon a change in the ADS(s)-to-ordinary share(s) ratio, or for any other reason), excluding ADS issuances as a result of distributions described in the fourth bullet below | Up to U.S. 5¢ per ADS issued |
| • Cancellation of ADSs (e.g., a cancellation of ADSs for delivery of deposited ordinary shares, upon a change in the ADS(s)-to-ordinary share(s) ratio, or for any other reason) | Up to U.S. 5¢ per ADS cancelled |
| • Distribution of cash dividends or other cash distributions (e.g., upon a sale of rights and other entitlements) | Up to U.S. 5¢ per ADS held |
| • Distribution of ADSs pursuant to (i) stock dividends or other free stock distributions, or (ii) exercise of rights to purchase additional ADSs | Up to U.S. 5¢ per ADS held |
| • Distribution of securities other than ADSs or rights to purchase additional ADSs (e.g., upon a spin-off) | Up to U.S. 5¢ per ADS held |
| • ADS Services | Up to U.S. 5¢ per ADS held on the applicable record date(s) established by the depositary bank |
| • Registration of ADS transfers (e.g., upon a registration of the transfer of registered ownership of ADSs, upon a transfer of ADSs into DTC and *vice versa*, or for any other reason) | Up to U.S. 5¢ per ADS (or fraction thereof) transferred |
| • Conversion of ADSs of one series for ADSs of another series (e.g., upon conversion of Partial Entitlement ADSs for Full Entitlement ADSs, or upon conversion of Restricted ADSs (each as defined in the Deposit Agreement) into freely transferable ADSs, and *vice versa*). | Up to U.S. 5¢ per ADS (or fraction thereof) converted |

As an ADS holder you will also be responsible to pay certain charges such as:

- taxes (including applicable interest and penalties) and other governmental charges;
- the registration fees as may from time to time be in effect for the registration of ordinary shares on the share register and applicable to transfers of ordinary shares to or from the name of the custodian, the depositary bank or any nominees upon the making of deposits and withdrawals, respectively;
- certain cable, telex and facsimile transmission and delivery expenses;
- the fees, expenses, spreads, taxes and other charges of the depositary bank and/or service providers (which may be a division, branch or affiliate of the depositary bank) in the conversion of foreign currency;
- the reasonable and customary out-of-pocket expenses incurred by the depositary bank in connection with compliance with exchange control regulations and other regulatory requirements applicable to ordinary shares, ADSs and ADRs; and
- the fees, charges, costs and expenses incurred by the depositary bank, the custodian, or any nominee in connection with the ADR program.

ADS fees and charges for (i) the issuance of ADSs, and (ii) the cancellation of ADSs are charged to the person for whom the ADSs are issued (in the case of ADS issuances) and to the person for whom ADSs are cancelled (in the case of ADS cancellations). In the case of ADSs issued by the depositary bank into DTC, the ADS issuance and cancellation fees and charges may be deducted from distributions made through DTC, and may be charged to the DTC participant(s) receiving the ADSs being issued or the DTC participant(s) holding the ADSs being cancelled, as the case may be, on behalf of the beneficial owner(s) and will be charged by the DTC participant(s) to the account of the applicable beneficial owner(s) in accordance with the procedures and practices of the DTC participants as in effect at the time. ADS fees and charges in respect of distributions and the ADS service fee are charged to the holders as of the applicable ADS record date. In the case of distributions of cash, the amount of the applicable ADS fees and charges is deducted from the funds being distributed. In the case of (i) distributions other than cash and (ii) the ADS service fee, holders as of the ADS record date will be invoiced for the amount of the ADS fees and charges and such ADS fees and charges may be deducted from distributions made to holders of ADSs. For ADSs held through DTC, the ADS fees and charges for distributions other than cash and the ADS service fee may be deducted from distributions made through DTC, and may be charged to the DTC participants in accordance with the procedures and practices prescribed by DTC and the DTC participants in turn charge the amount of such ADS fees and charges to the beneficial owners for whom they hold ADSs. In the case of (i) registration of ADS transfers, the ADS transfer fee will be payable by the ADS Holder whose ADSs are being transferred or by the person to whom the ADSs are transferred, and (ii) conversion of ADSs of one series for ADSs of another series, the ADS conversion fee will be payable by the Holder whose ADSs are converted or by the person to whom the converted ADSs are delivered.

In the event of refusal to pay the depositary bank fees, the depositary bank may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary bank fees from any distribution to be made to the ADS holder. Certain depositary fees and charges (such as the ADS services fee) may become payable shortly after the closing of the ADS offering. Note that the fees and charges you may be required to pay may vary over time and may be changed by us and by the depositary bank. You will receive prior notice of such changes. The depositary bank may reimburse us for certain expenses incurred by us in respect of the ADR program, by making available a portion of the ADS fees charged in respect of the ADR program or otherwise, upon such terms and conditions as we and the depositary bank agree from time to time.

**Amendments and Termination**

We may agree with the depositary bank to modify the deposit agreement at any time without your consent. We undertake to give holders 30 days' prior notice of any modifications that would materially prejudice any of

their substantial rights under the deposit agreement. We will not consider to be materially prejudicial to your substantial rights any modifications or supplements that are reasonably necessary for the ADSs to be registered under the Securities Act or to be eligible for book-entry settlement, in each case without imposing or increasing the fees and charges you are required to pay. In addition, we may not be able to provide you with prior notice of any modifications or supplements that are required to accommodate compliance with applicable provisions of law.

You will be bound by the modifications to the deposit agreement if you continue to hold your ADSs after the modifications to the deposit agreement become effective. The deposit agreement cannot be amended to prevent you from withdrawing the ordinary shares represented by your ADSs (except as permitted by law).

We have the right to direct the depositary bank to terminate the deposit agreement. Similarly, the depositary bank may in certain circumstances on its own initiative terminate the deposit agreement. In either case, the depositary bank must give notice to the holders at least 30 days before termination. Until termination, your rights under the deposit agreement will be unaffected.

After termination, the depositary bank will continue to collect distributions received (but will not distribute any such property until you request the cancellation of your ADSs) and may sell the securities held on deposit. After the sale, the depositary bank will hold the proceeds from such sale and any other funds then held for the holders of ADSs in a non-interest bearing account. At that point, the depositary bank will have no further obligations to holders other than to account for the funds then held for the holders of ADSs still outstanding (after deduction of applicable fees, taxes and expenses).

In connection with any termination of the deposit agreement, the depositary bank may make available to owners of ADSs a means to withdraw the ordinary shares represented by ADSs and to direct the depositary of such ordinary shares into an unsponsored American depositary share program established by the depositary bank. The ability to receive unsponsored American depositary shares upon termination of the deposit agreement would be subject to satisfaction of certain U.S. regulatory requirements applicable to the creation of unsponsored American depositary shares and the payment of applicable depositary fees.

**Books of Depositary**

The depositary bank will maintain ADS holder records at its depositary office. You may inspect such records at such office during regular business hours but solely for the purpose of communicating with other holders in the interest of business matters relating to the ADSs and the deposit agreement.

The depositary bank will maintain in New York facilities to record and process the issuance, cancellation, combination, split-up and transfer of ADSs. These facilities may be closed from time to time, to the extent not prohibited by law.

**Limitations on Obligations and Liabilities**

The deposit agreement limits our obligations and the depositary bank's obligations to you. Please note the following:

- We and the depositary bank are obligated only to take the actions specifically stated in the deposit agreement without negligence or bad faith.
- The depositary bank disclaims any liability for any failure to carry out voting instructions, for any manner in which a vote is cast or for the effect of any vote, provided it acts in good faith and in accordance with the terms of the deposit agreement.
- The depositary bank disclaims any liability for any failure to determine the lawfulness or practicality of any action, for the content of any document forwarded to you on our behalf or for the accuracy of any

translation of such a document, for the investment risks associated with investing in ordinary shares, for the validity or worth of the ordinary shares, for any tax consequences that result from the ownership of ADSs, for the credit-worthiness of any third party, for allowing any rights to lapse under the terms of the deposit agreement, for the timeliness of any of our notices or for our failure to give notice.

- We and the depositary bank also disclaim any liability for any action or inaction of any clearing or settlement system (and any participant thereof) for the ADSs or securities on deposit.
- We and the depositary bank will not be obligated to perform any act that is inconsistent with the terms of the deposit agreement.
- We and the depositary bank disclaim any liability if we or the depositary bank are prevented or forbidden from or subject to any civil or criminal penalty or restraint on account of, or delayed in, doing or performing any act or thing required by the terms of the deposit agreement, by reason of any provision, present or future of any law or regulation, or by reason of present or future provision of any provision of our Constitution, or any provision of or governing the securities on deposit, or by reason of any act of God or war or other circumstances beyond our control.
- We and the depositary bank disclaim any liability by reason of any exercise of, or failure to exercise, any discretion provided for in the deposit agreement or in our Constitution or in any provisions of or governing the securities on deposit.
- We and the depositary bank further disclaim any liability for any action or inaction in reliance on the advice or information received from legal counsel, accountants, any person presenting Shares for deposit, any holder of ADSs or authorized representatives thereof, or any other person believed by either of us in good faith to be competent to give such advice or information.
- We and the depositary bank also disclaim liability for the inability by a holder to benefit from any distribution, offering, right or other benefit that is made available to holders of ordinary shares but is not, under the terms of the deposit agreement, made available to you.
- We and the depositary bank may rely without any liability upon any written notice, request or other document believed to be genuine and to have been signed or presented by the proper parties.
- We and the depositary bank also disclaim liability for any consequential or punitive damages for any breach of the terms of the deposit agreement.
- No disclaimer of any Securities Act liability is intended by any provision of the deposit agreement.
- Nothing in the deposit agreement gives rise to a partnership or joint venture, or establishes a fiduciary relationship, among us, the depositary bank and you as ADS holder.
- Nothing in the deposit agreement precludes Citibank (or its affiliates) from engaging in transactions in which parties adverse to us or the ADS owners have interests, and nothing in the deposit agreement obligates Citibank to disclose those transactions, or any information obtained in the course of those transactions, to us or to the ADS owners, or to account for any payment received as part of those transactions.

**Taxes**

You will be responsible for the taxes and other governmental charges payable on the ADSs and the securities represented by the ADSs. We, the depositary bank and the custodian may deduct from any distribution the taxes and governmental charges payable by holders and may sell any and all property on deposit to pay the taxes and governmental charges payable by holders. You will be liable for any deficiency if the sale proceeds do not cover the taxes that are due.

The depositary bank may refuse to issue ADSs, to deliver, transfer, split and combine ADRs or to release securities on deposit until all taxes and charges are paid by the applicable holder. The depositary bank and the

custodian may take reasonable administrative actions to obtain tax refunds and reduced tax withholding for any distributions on your behalf. However, you may be required to provide to the depositary bank and to the custodian proof of taxpayer status and residence and such other information as the depositary bank and the custodian may require to fulfill legal obligations. You are required to indemnify us, the depositary bank and the custodian for any claims with respect to taxes based on any tax benefit obtained for you.

**Foreign Currency Conversion**

The depositary bank will arrange for the conversion of all foreign currency received into U.S. dollars if such conversion is practical, and it will distribute the U.S. dollars in accordance with the terms of the deposit agreement. You may have to pay fees and expenses incurred in converting foreign currency, such as fees and expenses incurred in complying with currency exchange controls and other governmental requirements.

If the conversion of foreign currency is not practical or lawful, or if any required approvals are denied or not obtainable at a reasonable cost or within a reasonable period, the depositary bank may take the following actions in its discretion:

- Convert the foreign currency to the extent practical and lawful and distribute the U.S. dollars to the holders for whom the conversion and distribution is lawful and practical.
- Distribute the foreign currency to holders for whom the distribution is lawful and practical.
- Hold the foreign currency (without liability for interest) for the applicable holders.

**Governing Law/Waiver of Jury Trial**

The deposit agreement, the ADRs and the ADSs will be interpreted in accordance with the laws of the State of New York. The rights of holders of ordinary shares (including ordinary shares represented by ADSs) are governed by the laws of Australia.

As an owner of ADSs or holder of an interest therein, you irrevocably agree that any suit, action or proceeding arising out of the Deposit Agreement, the ADSs, the ADRs or the transactions contemplated thereby, involving the Company or the Depositary, may only be instituted in a state or federal court in the city of New York, and by holding an ADS or an interest therein, you irrevocably waive any objection which you may now or hereafter have to the laying of venue of any such suit, action or proceeding in, and irrevocably submit to the exclusive jurisdiction of, such courts in any such suit, action or proceeding. The deposit agreement also provides that the foregoing agreement and waiver shall survive your ownership of the ADSs or interests therein.

**AS A PARTY TO THE DEPOSIT AGREEMENT, YOU IRREVOCABLY WAIVE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, YOUR RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT, OR RELATING TO, OF THE DEPOSIT AGREEMENT, THE ADRs OR ANY TRANSACTION CONTEMPLATED THEREIN.**

***Such waiver of your right to trial by jury would apply to any claim under U.S. federal securities laws. The waiver continues to apply to claims that arise during the period when a holder holds the ADSs, whether the ADS holder purchased the ADSs in this offering or in secondary transactions, even if the ADS holder subsequently withdraws the underlying ordinary shares. If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of the applicable case in accordance with applicable case law. However, you will not be deemed, by agreeing to the terms of the deposit agreement, to have waived our or the depositary's compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.***

## Shares Eligible for Future Sale

Prior to our initial public offering in December 2021, there was no public market in the United States for our securities and a liquid trading market for our ordinary shares may not develop or be sustained after this offering. Future sales of substantial amounts of our ordinary shares in the public market, including shares issued upon exercise of outstanding options and warrants, or the anticipation of these sales, could adversely affect prevailing market prices from time to time and could impair our ability to raise equity capital in the future.

Based on the number of shares of ordinary shares outstanding as of June 30, 2022, upon the completion of this offering we will have ordinary shares outstanding, assuming (1) no exercise of the underwriters' option to purchase additional ordinary shares and (2) no exercise of outstanding options or warrants. Of those shares, all of the shares sold in this offering and all shares sold in our initial public offering will be freely tradable, except that any shares held by our "affiliates," as that term is defined in Rule 144 under the Securities Act, or Rule 144, may only be sold in compliance with the limitations described below.

### Rule 144

In general, under Rule 144, any person who is not our affiliate and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell shares without restriction, subject to the availability of current public information about us. In addition, under Rule 144, any person who is not an affiliate of ours and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares without regard to whether current public information about us is available. A person who is our affiliate or who was our affiliate at any time during the preceding three months, and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our ordinary shares then outstanding, which will equal approximately shares immediately after this offering; or
- the average weekly trading volume of our ordinary shares on The NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales under Rule 144 by our affiliates are also subject to manner of sale provisions and notice requirements, and to the availability of current public information about us.

### Rule 701

In general, under Rule 701 of the Securities Act, any of our stockholders who purchased shares from us in connection with a qualified compensatory stock plan or other written agreement before we became subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act is eligible to resell those shares in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirements of Rule 144, and a non-affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirements of Rule 144 and without regard to the volume of such sales or the availability of public information about the issuer.

As of September 30, 2022, options to purchase a total of shares of ordinary shares were outstanding, of which were vested. There were also shares of ordinary shares outstanding pursuant to stock options that were early exercised that are subject to repurchase by the Company. In addition, there were shares of restricted ordinary shares issued since inception, of which are subject to repurchase by the Company as of September 30, 2022. Of the total number of shares of our ordinary shares issuable under the options referenced above, substantially all are eligible for sale unless held by an affiliate of ours.

**Lock-up agreements**

We, along with our directors, executive officers and stockholders with which our directors are affiliated, have agreed with the underwriters that for a period of 60 days after the closing of this offering, except with the prior written consent of Aegis Capital Corp. and subject to specified exceptions, we or they will not offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any ordinary shares or any securities convertible into or exercisable or exchangeable for ordinary shares, or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the ordinary shares.

Certain of our employees, including our executive officers and/or directors, may from time to time enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Except in limited circumstances, sales under these trading plans are not permitted until the expiration of the lock-up agreements relating to the offering described above.

**Equity incentive plans**

Our ordinary shares issued under the EEP and the ESOP are available for sale in the open market, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.

## Taxation

The following is a summary of material U.S. federal income tax considerations to U.S. Holders (as defined below) and material Australian income tax considerations to Non-Australian Shareholders (as defined below) of the acquisition, ownership and disposition of our ordinary shares and ADSs. This discussion is based on the laws in force as of the date of this prospectus, and is subject to changes in the relevant income tax law, including changes that could have retrospective effect. The following summary does not take into account or discuss the tax laws of any country or other taxing jurisdiction other than the United States and Australia. Holders are advised to consult their tax advisors concerning the overall tax consequences of the acquisition, ownership and disposition of ordinary shares and ADSs in their particular circumstances. This discussion is not intended, and should not be construed, as legal or professional tax advice.

### U.S. Federal Income Tax Considerations

The following discussion describes certain material U.S. federal income tax consequences to U.S. Holders (defined below) associated with the purchase, ownership and disposition of our ADSs or ordinary shares acquired pursuant to this offering. This summary applies only to investors that hold our ADSs or ordinary shares as capital assets within the meaning of Section 1221 of the Code, (generally, property held for investment) and that have the U.S. Dollar as their functional currency. This discussion is based on the Code and U.S. Treasury Regulations (including proposed U.S. Treasury Regulations), as well as judicial and administrative interpretations thereof, as of the date hereof. All of the foregoing authorities are subject to change, which change could apply retroactively and could affect the tax consequences described below. This summary does not discuss the alternative minimum tax, the Medicare tax on net investment income, any estate or gift tax consequences or the tax consequences of an investment in our ADSs or ordinary shares under the tax laws of any state of the United States or the District of Columbia or any political subdivision respectively thereof. No ruling will be requested from the U.S. Internal Revenue Service ("IRS") regarding the tax consequences of the purchase, ownership or disposition of our ADSs or ordinary shares, and there can be no assurance that the IRS will agree with the discussion set out below.

The following discussion does not address the tax consequences to any particular investor or to persons subject to special tax rules such as:

- banks, financial institutions or insurance companies;
- real estate investment trusts or regulated investment companies;
- brokers, dealers or traders in securities, commodities or currencies;
- tax-exempt entities, "individual retirement accounts" or "Roth IRAs" or governmental organizations;
- persons that received our ADSs or ordinary shares pursuant to the exercise of any employee stock option or otherwise as compensation for the performance of services;
- persons that will hold our ADSs or ordinary shares as part of a hedging, wash sale or conversion transaction or as part of a synthetic security or a position in a straddle for U.S. federal income tax purposes;
- U.S. expatriates;
- partnerships or other pass-through entities for U.S. federal income tax purposes, and persons that will hold our ADSs or ordinary shares through partnerships or other pass-through entities;
- holders that own or are deemed to own (directly, indirectly or by attribution) 10% or more, by voting power or value, of our outstanding ordinary shares; or
- persons that will hold the ADSs or ordinary shares in connection with a trade or business outside the United States.

For purposes of this discussion, a "U.S. Holder" is a beneficial owner of ADSs or ordinary shares that, for U.S. federal income tax purposes, is:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust that (1) is subject to the primary supervision of a court within the United States and the control of one or more United States persons for all substantial decisions or (2) has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a United States person.

If you are a partner in an entity treated as a partnership for U.S. federal income tax purposes that holds our ADSs or ordinary shares, your U.S. federal income tax treatment will generally depend on your status and the activities of the partnership. If you are a partner in such a partnership, you should consult your tax advisor.

The discussion below assumes the representations contained in the deposit agreement are true and that the obligations in the deposit agreement and any related agreement have been and will be complied with in accordance with their terms. For U.S. federal income tax purposes, a U.S. Holder of ADSs will generally be treated as the beneficial owner of the underlying ordinary shares represented by the ADSs. Assuming such treatment is respected, no gain or loss will be recognized upon an exchange of ADSs for ordinary shares. However, the creditability of any foreign taxes paid and the availability of the reduced tax rate for dividends received by certain non-corporate U.S. Holders, including individual U.S. Holders (as discussed below), could be affected by actions taken by intermediaries in the chain of ownership between the holders of ADSs and us if, as a result of such actions, the holders of ADSs are not properly treated as beneficial owners of underlying ordinary shares.

INVESTORS AND PROSPECTIVE PURCHASERS ARE URGED TO CONSULT THEIR TAX ADVISORS REGARDING THE APPLICATION OF THE U.S. FEDERAL INCOME TAX RULES TO THEIR PARTICULAR CIRCUMSTANCES AS WELL AS THE STATE, LOCAL, AND NON-U.S. TAX CONSEQUENCES TO THEM OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF THE ADSs OR ORDINARY SHARES.

*Dividends and Other Distributions on ADSs or ordinary shares*

Subject to the discussion below under "—Passive Foreign Investment Company Considerations," for U.S. federal income tax purposes, the gross amount of any distribution actually or constructively received with respect to your ADSs or ordinary shares, without reduction for any Australian taxes withheld therefrom, generally will be a foreign source dividend includible in your income as ordinary income to the extent such distributions are paid out of our current or accumulated earnings and profits as determined under U.S. federal income tax principles. To the extent that the amount of the distribution exceeds our current and accumulated earnings and profits, it will be treated first as a tax-free return of your tax basis in your ADSs or ordinary shares, and to the extent the amount of the distribution exceeds your tax basis, the excess will be taxed as capital gain. We do not currently, and we do not intend to, calculate our earnings and profits under U.S. federal income tax principles. Therefore, a U.S. Holder should expect that a distribution will be reported as a dividend even if that distribution would otherwise be treated as a return of capital or as a capital gain under the rules described above. Dividends will not be eligible for the dividends-received deduction allowed to corporations in respect of dividends received from other U.S. corporations.

Subject to applicable limitations, with respect to certain non-corporate U.S. Holders (including individual U.S. Holders), dividends will generally constitute "qualified dividend income" that is taxed at the lower

applicable capital gains rate, provided that (1) we are eligible for the benefits of the income tax treaty between the United States and Australia ("Treaty") or the ADSs or ordinary shares are readily tradable on an established securities market in the United States, including the Nasdaq, (2) we are not a PFIC for either the taxable year in which the dividend was paid or the preceding taxable year, and (3) certain holding period requirements are met. You should consult your tax advisor regarding the availability of the lower rate for dividends with respect to our ADSs or ordinary shares.

The amount of any distribution paid in Australian Dollars that will be included in your gross income will be equal to the U.S. Dollar value of the distribution, calculated using the exchange rate in effect on the date you receive the dividend, regardless of whether the payment is actually converted into U.S. Dollars. Any gain or loss resulting from foreign currency exchange rate fluctuations during the period from the date the dividend is received to the date the Australian Dollars are converted into U.S. Dollars will be treated as ordinary income or loss, and generally will be income or loss from sources within the United States for U.S. foreign tax credit purposes. If the Australian Dollars are converted into U.S. Dollars on the date of receipt, you generally should not be required to recognize foreign currency gain or loss in respect of the dividend. The amount of any distribution of property other than cash generally will be the fair market value of such property on the date of distribution.

Subject to certain conditions and limitations, any Australian taxes withheld from a distribution to you may be eligible for credit against your U.S. federal income tax liability. If the dividends are qualified dividend income (as discussed above), the amount of the dividend taken into account for purposes of calculating the U.S. foreign tax credit limitation generally will be limited to the gross amount of the dividend, multiplied by the reduced rate divided by the highest rate of tax normally applicable to dividends. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends that we distribute generally will constitute "passive category income" but could, in the case of certain U.S. Holders, constitute "general category income." The rules governing the U.S. foreign tax credit are complex, and you should consult your tax advisors to determine whether and to what extent a credit would be available in your particular circumstances, including the effects of any applicable income tax treaty. A U.S. Holder that does not elect to claim a foreign tax credit with respect to any foreign taxes for a given taxable year may instead claim an itemized deduction for all foreign taxes paid or accrued in that taxable year.

*Sale, Exchange or Other Taxable Disposition of ADSs or Ordinary Shares*

Subject to the discussion below under "—Passive Foreign Investment Company Considerations," you will recognize capital gain or loss on a sale, exchange or other taxable disposition of your ADSs or ordinary shares equal to the difference between the amount realized (in U.S. Dollars) on such disposition and your adjusted tax basis (in U.S. Dollars) in your ADSs or ordinary shares. If you are a non-corporate U.S. Holder (including an individual U.S. Holder) who has held ADSs or ordinary shares for more than one year, capital gain on a disposition of ADSs or ordinary shares generally will be eligible for reduced U.S. federal income tax rates. Any gain or loss that you recognize generally will be treated as U.S.-source income or loss for U.S. foreign tax credit purposes. The deductibility of capital losses is subject to limitations.

If you receive foreign currency on the disposition of ADSs or ordinary shares, the amount realized generally will be the U.S. Dollar value of the payment received determined on the date of the disposition. If the ADSs or ordinary shares are treated as traded on an "established securities market," a cash basis U.S. Holder (or an accrual basis U.S. Holder that makes a special election that must be applied consistently from year to year and cannot be changed without the consent of the IRS) will determine the U.S. Dollar value of the amount realized in foreign currency by translating the amount received at the spot rate of exchange on the settlement date of the disposition. If you are an accrual basis taxpayer that is not eligible to or does not elect to determine the amount realized using the spot rate on the settlement date, you will recognize foreign currency gain or loss to the extent of any difference between the U.S. Dollar amount realized on the date of disposition and the U.S. Dollar value of

the currency received at the spot rate on the settlement date. Your initial tax basis in your ADSs or ordinary shares will be your U.S. Dollar cost of your ADSs or ordinary shares determined on the date of purchase. However, if the ADSs or ordinary shares are treated as traded on an established securities market and you are either a cash basis U.S. Holder or an accrual basis taxpayer who has made the special election described above, you will use the U.S. Dollar cost determined on the settlement date of the purchase.

*Passive Foreign Investment Company Considerations*

A non-U.S. corporation will be classified as a PFIC for any taxable year in which, after applying certain look- through rules, either:

- at least 75% of its gross income is passive income; or
- at least 50% of its assets (generally based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income.

For purposes of the above calculations, a non-U.S. corporation will be treated as owning its proportionate share of the assets and earning its proportionate share of the income of any other corporation in which it owns, directly or indirectly, 25% or more (by value) of the equity. Passive income generally includes dividends, interest, certain rents or royalties, foreign currency or other investment gains and certain other categories of income.

Based on the value of our assets for our taxable year ending June 30, 2022, including the value of our goodwill, and the composition of our income and assets in such taxable year, we do not believe that we were a PFIC for our taxable year ending June 30, 2022. However, the application of the PFIC rules is subject to uncertainty in several respects. Furthermore, a separate determination must be made after the close of each taxable year as to whether we are a PFIC for that year, based on our income for the entire year and the value of our assets throughout the year. Accordingly, we cannot assure you that we were not a PFIC for our taxable year ending June 30, 2022 or that we will not be a PFIC for our current taxable year or any future taxable year. In particular, our PFIC status may depend, in part, on the receipt and treatment of other sources of income (including government grants) and having active income from other sources in excess of passive income from investments. For purposes of the asset test described above, goodwill is generally characterized as an active asset to the extent it is associated with business activities that produce active income, and the value of our assets, including goodwill, generally will be calculated using the market price of our ADSs or ordinary shares, which may fluctuate considerably, especially in times of high market volatility. Accordingly, fluctuations in the market price of our ADSs or ordinary shares may affect our PFIC status for any taxable year. In addition, cash is generally characterized as a passive asset for these purposes, so the composition of our income and assets will be affected by how, and how quickly, we spend the cash raised that we hold, including the cash raised in this offering.

If we are classified as a PFIC in any taxable year with respect to which a U.S. Holder owns the ADSs or ordinary shares, we will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns the ADSs or ordinary shares, regardless of whether we continue to meet the tests described above unless (1) we cease to be a PFIC and (2) the U.S. Holder has made a “deemed sale” election under the PFIC rules.

If we are a PFIC for any taxable year during which you hold ADSs or ordinary shares and you do not make one of the elections described above or below, you will be subject to special tax rules with respect to any “excess distribution” that you receive and any gain you realize from a sale or other disposition (including a pledge) of ADSs or ordinary shares. Distributions you receive in a taxable year that are greater than 125% of the average annual distributions you received during the shorter of the three preceding taxable years or your holding period for the ADSs or ordinary shares will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over your holding period for the ADSs or ordinary shares;

- the amount allocated to the current taxable year, and any taxable year prior to the first taxable year in which we became a PFIC, will be treated as ordinary income; and
- the amount allocated to each other year will be subject to the highest tax rate in effect for that year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to years prior to the year of disposition or "excess distribution" cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale of the ADSs or ordinary shares cannot be treated as capital, even if you hold the ADSs or ordinary shares as capital assets.

Certain elections may be available that would result in alternative treatments (such as mark-to-market treatment of the ADSs or ordinary shares). There can be no assurance that we will provide the information necessary for U.S. Holders of our ADSs or ordinary shares to make qualified electing fund elections, which, if available, would result in tax treatment different from the general tax treatment for an investment in a PFIC described above.

If we are treated as a PFIC with respect to you for any taxable year, to the extent any of our subsidiaries are also PFICs, you may be deemed to own shares in such lower-tier PFICs that are directly or indirectly owned by us in that proportion which the value of the ADSs or ordinary shares you own bears to the value of all of our ADSs or ordinary shares, and you may be subject to the adverse tax consequences described above with respect to the shares of such lower-tier PFICs that you would be deemed to own. However, an election for mark-to-market treatment would likely not be available with respect to any such subsidiaries. You should consult your tax advisors regarding the availability and desirability of a mark-to-market election as well as the impact of such election on interests in any lower-tier PFICs.

If we are considered a PFIC, a U.S. Holder will also be subject to information reporting requirements on an annual basis. If we are or become a PFIC, you should consult your tax advisor regarding any reporting requirements that may apply to you.

U.S. Holders are urged to consult their tax advisors regarding the application of the PFIC rules to the ownership and disposition of the ADSs or ordinary shares.

*Backup Withholding Tax and Information Reporting Requirements*

Dividends on and the proceeds of a sale or other taxable disposition of ADSs or ordinary shares may be subject to information reporting to the IRS and possible U.S. backup withholding. Backup withholding will not apply to a U.S. Holder who furnishes a correct taxpayer identification number and makes any other required certification or who is otherwise exempt from backup withholding. U.S. Holders who are required to establish their exempt status can provide such certification on IRS Form W-9. U.S. Holders should consult their tax advisors regarding the application of the U.S. information reporting and backup withholding rules.

Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a U.S. Holder's U.S. federal income tax liability, and a U.S. Holder may obtain a refund of any excess amounts withheld under the backup withholding rules by timely filing the appropriate claim for refund with the IRS and furnishing any required information.

*Additional Reporting Requirements*

Individuals (and certain entities) that own "specified foreign financial assets" with an aggregate value in excess of certain thresholds on the last day of the taxable year (or with an aggregate value in excess of certain

thresholds at any time during the taxable year) are generally required to file an information report on IRS Form 8938 with respect to such assets with their U.S. federal income tax returns. "Specified foreign financial assets" include any financial accounts maintained by foreign financial institutions, as well as any of the following, but only if they are not held in accounts maintained by certain financial institutions: (1) stocks and securities issued by non-U.S. persons, (2) financial instruments and contracts held for investment that have non-U.S. issuers or counterparties, and (3) interests in foreign entities. The ADSs or ordinary shares may be subject to these rules. U.S. Holders are urged to consult their tax advisors regarding the application of these rules to their ownership of the ADSs or ordinary shares.

**Australian Tax Considerations**

In this section, we discuss the material Australian income tax, stamp duty and goods and services tax considerations related to the acquisition, ownership and disposal by the absolute beneficial owners of the ordinary shares or ADSs. This discussion represents the opinion of Johnson Winter & Slattery, Australian counsel to Bionomics.

This summary only discusses the tax considerations for Non-Australian Shareholders (as defined below). It is based upon existing Australian tax law, case law and administrative practice of various revenue authorities as of the date of this registration statement, which is subject to change, possibly retrospectively. This discussion does not address all aspects of Australian tax law which may be important to particular investors in light of their individual investment circumstances, such as shares held by investors subject to special tax rules (for example, financial institutions, insurance companies or tax exempt organizations). In addition, this summary does not discuss any foreign or state tax considerations, other than stamp duty.

Prospective investors are urged to consult their tax advisors regarding the Australian and foreign income and other tax considerations of the acquisition, ownership and disposition of the shares. As used in this summary a "Non-Australian Shareholder" is a holder that is not an Australian tax resident and is not carrying on business in Australia through a permanent establishment.

*Nature of ADSs for Australian Taxation Purposes*

Ordinary shares represented by ADSs held by a U.S. holder will be treated for Australian taxation purposes as held under a "bare trust" for such holder. Consequently, the underlying ordinary shares will be regarded as owned by the ADS holder for Australian income tax and capital gains tax purposes. Dividends paid on the underlying ordinary shares will also be treated as dividends paid to the ADS holder, as the person beneficially entitled to those dividends. Therefore, in the following analysis we discuss the tax consequences to Non-Australian Shareholders owning ordinary shares for Australian taxation purposes. We note that the holder of an ADS will be treated for Australian tax purposes as the owner of the underlying ordinary shares that are represented by such ADSs.

*Taxation of Dividends*

Australia operates a dividend imputation system under which dividends may be declared to be "franked" to the extent of tax paid on company profits from which the dividend is sourced. Fully franked dividends are not subject to dividend withholding tax when paid to Non-Australian Shareholders. An exemption for dividend withholding tax can also apply to unfranked dividends that are declared to be conduit foreign income ("CFI") and paid to Non-Australian Shareholders. Dividend withholding tax will be imposed at 30%, unless a shareholder is a resident of a country with which Australia has a double taxation agreement and qualifies for the benefits of the treaty. Under the provisions of the current Double Taxation Convention between Australia and the United States,
the Australian tax withheld on unfranked dividends that are not declared to be CFI paid by us to a resident of the
United States which is beneficially entitled to that dividend is limited to 15% where that resident is a qualified person for the purposes of the Double Taxation Convention between Australia and the United States.

If a Non-Australian Shareholder is a company that is a qualified person for the purposes of the Double Taxation Convention between Australia and the United States and owns a 10% or more interest, the Australian tax withheld on dividends paid by us to which a resident of the United States is beneficially entitled is limited to 5%. In limited circumstances the rate of withholding can be reduced to zero.

*Tax on Sales or other Dispositions of Shares—Capital gains tax*

Non-Australian Shareholders will not be subject to Australian capital gains tax on the gain made on a sale or other disposal of ordinary shares, unless they, together with their associates, hold 10% or more of our issued capital, at the time of disposal or for 12 months of the last 2 years prior to disposal and more than 50% of our direct or indirect assets, determined by reference to market value, consists of Australian land, leasehold interests or Australian mining, quarrying or prospecting rights. The Double Taxation Convention between the United States and Australia does not limit Australia's right to tax any gain in these circumstances. Net capital gains are calculated after reduction for capital losses, which may only be offset against capital gains.

*Tax on Sales or other Dispositions of Shares—Shareholders Holding Shares on Revenue Account*

Some Non-Australian Shareholders may hold shares on revenue rather than on capital account for example, share traders. These shareholders may have the gains made on the sale or other disposal of the shares included in their assessable income under the ordinary income taxing provisions of the income tax law, if the gains are sourced in Australia.

Non-Australian Shareholders assessable under these ordinary income provisions in respect of gains made on shares held on revenue account would be assessed for such gains at the Australian tax rates for non-Australian residents, which start at a marginal rate of 32.5% for individuals. Some relief from Australian income tax may be available to Non-Australian Shareholders under the Double Taxation Convention between the United States and Australia.

To the extent an amount would be included in a Non-Australian Shareholder's assessable income under both the capital gains tax provisions and the ordinary income provisions, the capital gain amount would generally be reduced, so that the shareholder would not be subject to double tax on any part of the income gain or capital gain.

*Dual Residency*

If a shareholder is a resident of both Australia and the United States under those countries' domestic taxation laws, that shareholder may be subject to tax as an Australian resident. If, however, the shareholder is deemed to be a U.S. resident for the purposes of the Double Taxation Convention between the United States and Australia, the Australian tax would be subject to limitation by the Double Taxation Convention. Shareholders should obtain specialist taxation advice in these circumstances.

*Stamp Duty*

In general terms, no stamp duty is payable on the issue and trading of shares that are quoted on the ASX or Nasdaq. However, stamp duty may be payable if there is an acquisition of 90% or more of all of our issued shares in certain circumstances.

No Australian stamp duty is payable on the issue and trading of ADSs.

*Australian Estate Taxes / Death Duty*

Australia does not have any form of estate tax or death duty. As a general rule, no Australian capital gains tax liability is realized upon the inheritance of a deceased person's shares. The disposal of inherited shares by beneficiaries may, however, give rise to a capital gains tax liability if the gain falls within the scope of Australia's jurisdiction to tax.

*Goods and Services Tax*

The issue or transfer of shares to a non-Australian resident investor will not incur Australian goods and services tax.

## Underwriting

Aegis Capital Corp. is acting as the representative of the underwriters of the offering. Aegis Capital Corp. and Berenberg Capital Markets LLC are acting as joint book-running managers of this offering. Subject to the terms and conditions stated in the underwriting agreement dated the date of this prospectus, each underwriter named below has severally agreed to purchase, and we have agreed to sell to that underwriter, the number of ADSs set forth opposite the underwriter's name.

| Underwriters | Number of ADSs |
|---|---|
| Aegis Capital Corp. | |
| Berenberg Capital Markets LLC | |
| Total | |

The underwriting agreement provides that the obligations of the underwriters to purchase the ADSs included in this offering is subject to approval of legal matters by counsel and to other conditions. The underwriters are obligated to purchase all of the ADSs (other than those covered by the over-allotment option described below) if they purchase any of the ADSs. The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, the underwriting agreement provides that the obligations of the underwriters to pay for and accept delivery of the ADSs offered by us in this prospectus are subject to various representations and warranties and other customary conditions specified in the underwriting agreement.

ADSs sold by the underwriters to the public will initially be offered at the offering price set forth on the cover of this prospectus. If all of the ADSs are not sold at the initial offering price, the underwriters may change the offering price and the other selling terms. The representative has advised us that the underwriters do not intend to make sales to discretionary accounts.

We have granted to the underwriters an option, exercisable for 30 days after the closing date of this offering, to purchase up to additional ADSs at the offering price less the underwriting discount. To the extent the option is exercised, each underwriter must purchase a number of additional ADSs approximately proportionate to that underwriter's initial purchase commitment. Any ADSs issued or sold under the option will be issued and sold on the same terms and conditions as the other ADSs that are the subject of this offering.

We, our executive officers and directors, employees and shareholders with representation on the Company's board of directors holding at least ten percent (10%) of the outstanding ordinary shares have agreed that, for a period of sixty (60) days from the closing date of this offering, we and they will not, without the prior written consent of the representative, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of any ADSs or ordinary shares or any securities convertible into or exercisable or exchangeable for ADSs or ordinary shares, subject to certain exceptions, including exceptions allowing the transfer of ordinary shares purchased in the offering and open market purchases following the offering. Aegis Capital Corp. in its sole discretion may release any of the securities subject to these lock-up agreements at any time, which in the case of our executive officers and directors, shall be with notice.

Our ordinary shares have been trading on the Australian Securities Exchange, or the ASX, since December 1999 under the symbol "BNO."

Our ADSs are listed on the Nasdaq Global Market under the symbol "BNOX."

ADSs sold by the underwriters to the public will offered at the offering price set forth on the cover page of this prospectus. The underwriters may offer ADSs to securities dealers at that price less a concession of not more than $ per ADS. After the initial offering to the public, the public offering price and other selling terms may be changed by the representative.

The following table shows the underwriting discounts and commissions that we are to pay to the underwriters in connection with this offering (which represent 7.0% of total offering proceeds).

| | Per ADS | No Exercise | Full Exercise |
|---|---|---|---|
| Public offering price | | | |
| Underwriting discounts and commissions | | | |
| Proceeds to us, before expenses | | | |
| Total | | | |

These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional ADSs.

In connection with the offering, the underwriters may purchase and sell ADSs in the open market. Purchases and sales in the open market may include short sales and purchases to cover short positions, which may include purchases pursuant to the underwriters' option to purchase additional ADSs.

- Short sales involve secondary market sales by the underwriters of a greater number of ADSs than they are required to purchase in the offering.
- "Covered" short sales are sales of ADSs in an amount up to the number of ADSs represented by the underwriters' option.
- "Naked" short sales are sales of ADSs in an amount in excess of the number of ADSs represented by the underwriters' option.
- Covering transactions involve purchases of ADSs either pursuant to the option or in the open market after the distribution has been completed in order to cover short positions.
- To close a naked short position, the underwriters must purchase ADSs in the open market after the distribution has been completed. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the ADSs in the open market after pricing that could adversely affect investors who purchase in the offering.
- To close a covered short position, the underwriters must purchase ADSs in the open market after the distribution has been completed or must exercise the option. In determining the source of ADSs to close the covered short position, the underwriters will consider, among other things, the price of ADSs available for purchase in the open market as compared to the price at which they may purchase ADSs through the option.

The underwriters may conduct these transactions in the over-the-counter market or otherwise. If the underwriters commence any of these transactions, they may discontinue them at any time.

We estimate that the total expenses of this offering payable by us will be $ , excluding underwriting discounts and commissions. We have agreed to pay the underwriters a non-accountable expense allowance equal to 1.0% of the total gross proceeds of the offering. We have also agreed to pay all expenses relating to the offering, including: (a) all filing fees and expenses relating to the registration of the securities with the Commission; (b) all fees and expenses relating to the listing of the ADSs on Nasdaq; (c) all fees associated with the review of the offering by FINRA; (d) all fees, expenses and disbursements relating to the registration, qualification or exemption of ADSs offered under "blue sky" securities laws or the securities laws of foreign jurisdictions designated by the underwriters, including the reasonable fees and expenses of the underwriter's blue sky counsel; (e) all fees, expenses and disbursements relating to the registration, qualification or exemption of the ADSs under the securities laws of such foreign jurisdictions; (f) the costs of mailing and printing the offering materials; (g) transfer and/or stamp taxes, if any, payable upon our transfer of the ADSs to the underwriters; and (h) the fees and expenses of our accountants; and (i) $100,000 for reasonable legal fees and disbursements for the representative's legal counsel.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make because of any of those liabilities.

The underwriters are full-service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, principal investment, hedging, financial and brokerage activities. The underwriters and their affiliates may in the future engage in investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They may in the future receive customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates.

The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members. The representative may agree to allocate a number of ADSs to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of, nor incorporated by reference into, this prospectus, has not been approved or endorsed by us, and should not be relied upon by investors.

**Notice to Prospective Investors in Australia**

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia (the Australian Corporations Act), has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Australian Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Australian Corporations Act and that you have provided an accountant's certificate to us which complies with the requirements of section 708(8)(c)(i) or (ii) of the Australian Corporations Act and related regulations before the offer has been made;
- a person associated with us under section 708(12) of the Australian Corporations Act; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Australian Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Australian Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the securities issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Australian Corporations Act.

**Notice to Prospective Investors in Canada**

*(A) Resale Restrictions*

The distribution of ADSs in Canada is being made only in the provinces of Ontario, Quebec, Alberta, British Columbia, Manitoba, New Brunswick and Nova Scotia on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of these securities are made. Any resale of our ADSs in Canada must be made under applicable securities laws which may vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of the ADSs.

*(B) Representations of Canadian Purchasers*

By purchasing our ADSs in Canada and accepting delivery of a purchase confirmation, a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

- the purchaser is entitled under applicable provincial securities laws to purchase our ADSs without the benefit of a prospectus qualified under those securities laws as it is an "accredited investor" as defined under National Instrument 45-106-Prospectus Exemptions or Section 73.3(1) of the Securities Act (Ontario), as applicable,
- the purchaser is a "permitted client" as defined in National Instrument 31-103-Registration Requirements, Exemptions and Ongoing Registrant Obligations,
- where required by law, the purchaser is purchasing as principal and not as agent, and
- the purchaser has reviewed the text above under Resale Restrictions.

*(C) Conflicts of Interest*

Canadian purchasers are hereby notified that certain of the underwriters are relying on the exemption set out in section 3A.3 or 3A.4, if applicable, of National Instrument 33-105-Underwriting Conflicts from having to provide certain conflict of interest disclosure in this document.

*(D) Statutory Rights of Action*

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if the prospectus (including any amendment thereto) such as this document contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser of these securities in Canada should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

*(E) Enforcement of Legal Rights*

All of our directors and officers as well as the experts named herein may be located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

*(F) Taxation and Eligibility for Investment*

Canadian purchasers of ADSs should consult their own legal and tax advisors with respect to the tax consequences of an investment in our ADSs in their particular circumstances and about the eligibility of our ADSs for investment by the purchaser under relevant Canadian legislation.

**Notice to Prospective Investors in the European Economic Area**

In relation to each Member State of the European Economic Area (each, a Relevant State), no ADSs have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the ADSs which have been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that the ADSs may be offered to the public in that Relevant State at any time:

- to any legal entity which is a "qualified investor" as defined under Article 2 of the Prospectus Regulation;
- to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of the underwriters or the underwriters nominated by us for any such offer; or
- in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of ADSs shall require us or any representative to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer ADSs to the public" in relation to the ADSs in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and the ADSs to be offered so as to enable an investor to decide to purchase or subscribe to the ADSs, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

**Notice to Prospective Investors in Hong Kong**

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong (SFO) and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong (CO) or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

**Notice to Prospective Investors in Israel**

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968 (the Israeli Securities Law) and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the ADSs is directed only at, (i) a

limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum to the Israeli Securities Law (the Israeli Addendum), consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals," each as defined in the Israeli Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Israeli Addendum, for the accounts of their clients who are investors listed in the Israeli Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Israeli Addendum, are aware of the meaning of same and agree to it.

**Notice to Prospective Investors in Japan**

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended) (FIEL), and the underwriters will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

**Notice to Prospective Investors in Singapore**

This prospectus has not been and will not be lodged or registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the ADSs may not be circulated or distributed, nor may the ADSs be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the SFA), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the notes are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the notes pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

**Notice to Prospective Investors in Switzerland**

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (SIX) or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the Company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

**Notice to Prospective Investors in the United Kingdom**

No ADSs have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the ADSs which has been approved by the Financial Conduct Authority, except that the ADSs may be offered to the public in the United Kingdom at any time:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representative for any such offer; or

(c) in any other circumstances falling within Section 86 of the Financial Services and Markets Act of 2002 (the FSMA).

provided that no such offer of the ADSs shall require the Issuer or any Manager to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to the ADSs in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any ADSs to be offered so as to enable an investor to decide to purchase or subscribe for any ADSs and the expression “UK Prospectus Regulation” means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

**Expenses of this Offering**

The following table sets forth the costs and expenses, other than the underwriting commissions, payable by us in connection with the sale of ADSs being registered. All amounts are estimates except for the SEC, registration fee, the Financial Industry Regulatory Authority ("FINRA") filing fee and the Nasdaq Global Market listing fee.

| | Amount |
|---|---|
| Securities and Exchange Commission registration fee | $ 635 |
| FINRA filing fee | 1,400 |
| Accountants' fees and expenses | $ 51,000 |
| Legal fees and expenses | $ 220,000 |
| Printing and engraving expenses | $ 120,000 |
| Miscellaneous | $ 75,000 |
| Total expenses | $ 468,035 |

* To be filed by amendment

## Legal Matters

The validity of the ordinary shares represented by the ADSs and certain other matters under Australian law will be passed upon for us by Johnson Winter & Slattery, our Australian counsel. Certain matters of U.S. law will be passed upon for us by Latham & Watkins LLP. The underwriters are being represented by Kaufman & Canoles, P.C., Richmond, Virginia with respect to U.S. law.

## Experts

The consolidated financial statements of Bionomics Limited appearing in Bionomics Limited's Annual Report (Form 20-F) for the year ended June 30, 2022 have been audited by Ernst & Young, independent registered public accounting firm, as set forth in their report thereon, included therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

## Change in Accountants

On February 12, 2021, the resignation of Deloitte Touche Tohmatsu from its role as our independent accountants became effective.

During the year ended June 30, 2020 and through February 12, 2021, there were no disagreements between us and Deloitte Touche Tohmatsu on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreement, if not resolved to the satisfaction of Deloitte Touche Tohmatsu, would have caused them to make reference to the subject matter of the disagreement in connection with their reports on the financial statements for such years. During the year ended June 30, 2020 and through February 12, 2021, there were no reportable events (as defined in Regulation S-K Item 304(a)(1)(v)).

On December 11, 2020, our Board approved, subject to the effective date of the resignation of Deloitte Touche Tohmatsu as auditors for Australian financial reporting purposes, the engagement of Ernst & Young as our independent registered public accounting firm for Australian reporting purposes for the year ended June 30, 2021. Ernst & Young were subsequently appointed to perform the audit of our consolidated financial statements as of and for the year ended June 30, 2022 in connection with this offering.

During the years ended June 30, 2020 and June 30, 2021, and in the subsequent interim period through February 12, 2021, neither we nor anyone on our behalf consulted with Ernst & Young regarding either: (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on our financial statements, and neither was a written report provided to us nor was oral advice provided to us that Ernst & Young concluded was an important factor considered by us in reaching a decision as to the accounting, auditing or financial reporting issue; or (ii) 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.

We delivered a copy of this disclosure to Deloitte Touche Tohmatsu and requested that they furnish us a letter addressed to the SEC stating whether they agree with the above statements. In their letter to the SEC dated November 19, 2021, attached as Exhibit 16.1 to the registration statement of which this prospectus forms a part, Deloitte Touche Tohmatsu states that they agree with the statements above concerning their firm.

## Enforceability of Civil Liabilities

We are a public company incorporated under the laws of Australia. A majority of our directors and executive officers are non-residents of the United States, and all or substantially all of the assets of such persons are located outside the United States. As a result, it may not be possible for you to:

- effect service of process within the United States upon our non-U.S. resident directors and executive officers or on us;
- enforce in U.S. courts judgments obtained against our non-U.S. resident directors and executive officers or us in U.S. courts in any action, including actions under the civil liability provisions of U.S. securities laws;
- enforce in U.S. courts judgments obtained against any of our non-U.S. resident directors and executive officers or us in courts of jurisdictions outside the United States in any action, including actions under the civil liability provisions of U.S. securities laws; or
- to bring an original action in an Australian court to enforce liabilities against any of our non-U.S. resident directors and executive officers or us based solely upon U.S. securities laws.

You may also have difficulties enforcing in courts outside the United States judgments obtained in U.S. courts against any of our non-U.S. resident directors and executive officers or us, including actions under the civil liability provisions of U.S. securities laws.

With that noted, there are no treaties between Australia and the United States that would affect the recognition or enforcement of foreign judgments in Australia. We also note that investors may not be able to bring an original action in an Australian court against us to enforce liabilities based in part upon U.S. federal securities laws.

We have appointed CSC-Lawyers Incorporating Service, as our agent to receive service of process with respect to any action brought against us in the United States under U.S. federal securities laws or any action brought against us under U.S. state laws.

## Where You Can Find More Information

We have filed with the SEC a registration statement on Form F-1 under the Securities Act with respect to the ordinary shares represented by the ADSs offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the ordinary shares represented by the ADSs offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. All information we file with the SEC is available through the SEC's Electronic Data Gathering, Analysis and Retrieval system, which may be accessed through the SEC's website at *www.sec.gov*. In addition, our public filings with the ASX may be accessed through the ASX's website at *www.asx.com.au*.

We are subject to periodic reporting and other informational requirements of the Exchange Act as applicable to foreign private issuers. Our annual reports on Form 20-F for the year ending June 30, 2022 and subsequent years will be due within four months following the fiscal year end. We are not required to disclose certain other information that is required from U.S. domestic issuers. In our capacity as a foreign private issuer, we are exempt from certain rules under the Exchange Act that impose certain disclosure obligations and procedural requirements for proxy solicitations under Section 14 of the Exchange Act.

In addition, our officers, directors and principal shareholders are exempt from the reporting and 'short-swing' profit recovery provisions of Section 16 of the Exchange Act and the rules under the Exchange Act with respect to their purchases and sales of our ordinary shares or the ADSs. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. In addition, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information.

We are, however, still subject to the anti-fraud and anti-manipulation rules of the SEC, such as Rule 10b-5. Since many of the disclosure obligations required of us as a foreign private issuer are different than those required by companies filing as a domestic issuer, our shareholders, potential shareholders and the investing public in general should not expect to receive information about us in the same amount and at the same time as information is received from, or provided by, companies filing as a domestic issuer. We are liable for violations of the rules and regulations of the SEC, which apply to us as a foreign private issuer.

## INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to "incorporate by reference" information from other documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus.

We incorporate by reference into this prospectus and the registration statement of which this prospectus is a part the information or documents listed below that we have filed with the SEC:

1. Our Annual Report on Form 20-F for the fiscal year ended June 30, 2022, filed with the SEC on October 14, 2022; and
2. The description of our ordinary shares contained in our Registration Statement on Form 8-A filed with the SEC on December 13, 2021, as well as any subsequent amendments or reports filed for the purpose of updating such description.

The information incorporated by reference is considered to be part of this prospectus. Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus will be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus modifies, supersedes or replaces such statement.

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference in this prospectus, including exhibits to these documents. You should direct any requests for documents to Bionomics Limited., 200 Greenhill Road, Eastwood SA 5063, Australia, telephone: +61 881507400. You also may access these filings on our website at www.bionomics.com.au. We do not incorporate the information on our website into this prospectus and you should not consider any information on, or that can be accessed through, our website as part of this prospectus (other than those filings with the SEC that we specifically incorporate by reference into this prospectus).

# AMERICAN DEPOSITARY SHARES

# REPRESENTING ORDINARY SHARES


**AEGIS CAPITAL CORP.**

**BERENBERG**

## Part II

## INFORMATION NOT REQUIRED IN PROSPECTUS

### Item 6. Indemnification of Directors and Officers.

*Australian law*. Australian law provides that a company or a related body corporate of the company may provide for indemnification of officers and directors, except to the extent of any of the following liabilities incurred as an officer or director of the company:

- a liability owed to the company or a related body corporate of the company;
- a liability for a pecuniary penalty order made under section 1317G or a compensation order under section 961M, 1317H, 1317HA, 1317HB, 1317HC or 1317HE of the Corporations Act;
- a liability that is owed to someone other than the company or a related body corporate of the company and did not arise out of conduct in good faith; or
- legal costs incurred in defending an action for a liability incurred as an officer or director of the company if the costs are incurred:
- in defending or resisting proceedings in which the officer or director is found to have a liability for which they cannot be indemnified as set out above;
- in defending or resisting criminal proceedings in which the officer or director is found guilty;
- in defending or resisting proceedings brought by the ASIC or a liquidator for a court order if the grounds for making the order are found by the court to have been established (except costs incurred in responding to actions taken by the ASIC or a liquidator as part of an investigation before commencing proceedings for a court order); or
- in connection with proceedings for relief to the officer or a director under the Corporations Act, in which the court denies the relief.

*Constitution*. Our Constitution provides, except to the extent prohibited by the law and the Corporations Act and, to the extent that an officer or a director is not indemnified by any director and officer liability insurance maintained by us, for the indemnification of every person who is or has been an officer or a director of the company against liability incurred by that person as an officer or director. This includes any liability incurred by that person in their capacity as an officer or director of a related body corporate of the company.

The indemnification relates to any liability for costs and expenses incurred by the person in his or her capacity as our director or officer (i) in defending any proceedings, whether civil or criminal, in which judgment is given in favor of the person or in which the person is acquitted, and (ii) in connection with an application in which the court grants relief to the person under the Corporations Act. However the indemnity does not apply if the liability arises out of conduct on the part of the director or officer which involves a lack of good faith, or is contrary to our express instructions.

*Indemnification Agreements*. Pursuant to the terms of the Letter of Appointment between us and our directors, the form of which is filed as Exhibit 10.8 to this registration statement, we indemnify our directors against any liability incurred in connection with claims made by reason of being a director, to the extent our directors' and officers' insurance is inadequate, but subject to the limitations on indemnities outlined above.

*SEC Position*. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Pursuant to the underwriting agreement for this offering, the form of which is filed as Exhibit 1.1 to this registration statement, the underwriters will agree to indemnify our directors and officers and persons controlling us, within the meaning of the Securities Act, against certain liabilities that might arise out of or are based upon certain information furnished to us by any such underwriter.

**Item 7. Recent Sales of Unregistered Securities.**

The following list sets forth information as to all securities we have sold since July 1, 2018, which were not registered under the Securities Act.

1. On November 11, 2021, the Company issued 8,000,000 fully paid ordinary shares as a result of 8,000,000 warrants being exercised at their exercise price of A$0.06.

2. On September 2, 2021, the Company issued 2,000,000 fully paid ordinary shares as a result of 2,000,000 share options being exercised at their exercise price of A$0.0136.

3. On June 4, 2021, we issued 3,909,034 ordinary shares at A$0.145 per share for an aggregate offering price of A$566,810 to a number of institutional and sophisticated investors following the scaled back allocations as outlined to the ASX on April 6, 2021, pursuant to the Bionomics "Concurrent Placement" announcement to the ASX on March 17, 2021.

4. On April 8, 2021, we issued 17,228,346 ordinary shares at A$0.145 per share for an aggregate offering price of A$17,228,346 to a number of institutional and sophisticated investors pursuant to the Bionomics "Concurrent Placement" announced to the ASX on March 17, 2021 and issued 140,924,683 ordinary shares in an entitlement offer to our shareholders with Australian addresses at A$0.145 per share for an aggregate offering price of A$20,434,079.

5. On March 2, 2021, we issued 110,287,131 ordinary shares at A$0.145 per share for an aggregate offering price of A$15,991,634 under a placement to a number of North American and European institutional and sophisticated investors announced to the ASX on 9 February 2021 and issued warrants to Apeiron Investment Group Ltd to acquire 150,000,000 ordinary shares at A$0.06 per share.

6. On October 22, 2020, we issued 31,973,571 ordinary shares at A$0.0400 per share for an aggregate offering price of A$1,278,943, in a retail entitlement offer to shareholders with Australian addresses.

7. On October 6, 2020, we issued 22,330,875 ordinary shares at A$0.0400 per share for an aggregate offering price of A$893,235 in an institutional entitlement offer to institutional and sophisticated investors.

8. On September 24, 2020, we issued 54,333,000 ordinary shares at A$0.0400 per share for an aggregate offering price of A$2,173,320 a second placement to Apeiron Investment Group Ltd ("Apeiron") and four Exempt Investors nominated by Apeiron, pursuant to the Subscription Agreement announced to the ASX on June 2, 2020 and approved at the General Meeting of shareholders held on August 26, 2020.

9. On August 28, 2020, we issued 424,232 ordinary shares at A$0.1432 per share for an aggregate offering price of A$60,750 under the Employee Equity Plan as part of year ended June 30, 2020 Short Term Incentive award to Executives.

10. On June 30, 2020, we issued 81,500,00 ordinary shares at A$0.0400 per share for an aggregate offering price of A$3,260,000 under a placement to HSBC Custody Nominees (Australia) Limited, a nominee of Apeiron Investment Group Ltd, pursuant to the subscription agreement announced to the ASX on June 2, 2020.

11. On December 12, 2018, we issued 1,612,942 ordinary shares at A$0.1550 per share for an aggregate offering price of A$250,000 pursuant to the terms of a Share Purchase Plan pursuant to an offer dated November 22, 2018.

12. On November 16, 2018, we issued 60,169,738 ordinary shares at A$0.1637 per share for an aggregate offering price of A$9,849,787 under a placement to BVF Partners L.P. (and affiliates), as outlined in our announcement to the ASX on November 9, 2018.

13. On August 24, 2018, we issued 111,756 ordinary shares at A$0.4730 per share for an aggregate offering price of A$52,860 under the Employee Equity Plan as part of the fiscal year 2018 Short Term Incentive award to key management personnel and executive officers.

The transactions described above were made outside the United States pursuant to Regulation S or to U.S. persons pursuant to Rule 701 promulgated under the Securities Act, in that the securities were offered and sold either pursuant to written compensatory plans or pursuant to a written contract relating to compensation, as provided by Rule 701 or to U.S. persons pursuant to Section 4(a)(2) of the Securities Act in that such sales and issuances did not involve a public offering.

**Item 8. Exhibits and Financial Statement Schedules.**

**(a) Exhibits.** The list of exhibits is set forth under "Exhibit Index" at the end of this registration statement and is incorporated by reference herein.

**(b) Financial Statement Schedules.** Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

**Item 9. Undertakings.**

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

1. For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.

2. For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

## Exhibit Index

| Exhibit No. | Description | Incorporation by Reference | | | |
|---|---|---|---|---|---|
| | | Form | File No. | Exhibit No. | Filing Date |
| 1.1** | Form of Underwriting Agreement | | | | |
| 3.1 | Constitution of Bionomics Limited adopted at the 2021 Annual General Meeting | F-1/A | 333-261280 | 3.1 | 12/08/2021 |
| 4.1 | Form of Depositary Agreement between Bionomics adopted at the 2021 Annual General Meeting | F-1/A | 333-261280 | 4.1 | 12/13/2021 |
| 4.2 | Form of American Depositary Receipt evidencing American Depositary Shares (included in Exhibit 4.1) | F-1/A | 333-261280 | 4.2 | 12/13/2021 |
| 4.3 | Form of Warrant, issued December 12, 2016 | F-1 | 333-261280 | 4.3 | 11/22/2021 |
| 4.4 | Warrant Deed Poll, dated March 3, 2021 | F-1 | 333-261280 | 4.4 | 11/22/2021 |
| 5.1** | Opinion of Johnson Winter & Slattery | | | | |
| 10.1† | Bionomics Limited Employee Share Option Plan | F-1 | 333-261280 | 10.8 | 11/22/2021 |
| 10.2† | Bionomics Limited Employee Share Plan (A$1,000 Plan) – Terms of the Plan | F-1 | 333-261280 | 10.9 | 11/22/2021 |
| 10.3† | Bionomics Limited Employee Equity Plan – Plan Rules | F-1 | 333-261280 | 10.10 | 11/22/2021 |
| 10.4# | Research Collaboration and License Agreement, dated June 26, 2014, by and between Bionomics Limited and Merck Sharp & Dohme Corp. | F-1 | 333-261280 | 10.1 | 11/22/2021 |
| 10.5 | First Amendment to Research Collaboration and License Agreement, dated October 2, 2015, by and between Bionomics Limited and Merck Sharp & Dohme Corp. | F-1 | 333-261280 | 10.2 | 11/22/2021 |
| 10.6# | Second Amendment to Research Collaboration and License Agreement, dated May 9, 2016, by and between Bionomics Limited and Merck Sharp & Dohme Corp. | F-1 | 333-261280 | 10.3 | 11/22/2021 |
| 10.7# | Third Amendment to Research Collaboration and License Agreement, dated November 8, 2016, by and between Bionomics Limited and Merck Sharp & Dohme Corp. | F-1 | 333-261280 | 10.4 | 11/22/2021 |
| 10.8# | Fourth Amendment to Research Collaboration and License Agreement, dated April 26, 2017, by and between Bionomics Limited and Merck Sharp & Dohme Corp. | F-1 | 333-261280 | 10.5 | 11/22/2021 |
| 10.9# | IP License Agreement, dated November 18, 2020, by and between Bionomics Limited and Carina Biotech Pty Ltd. | F-1 | 333-261280 | 10.6 | 11/22/2021 |
| 10.10 | Lease by and between Bionomics Limited and 200 Greenhill Road PTY LTD, dated May 31, 2021 | F-1 | 333-261280 | 10.7 | 11/22/2021 |
| 10.11† | Bionomics Limited Executive Employment Agreement, dated June 30, 2021, between Bionomics Limited and Errol B. De Souza, Ph.D | F-1 | 333-261280 | 10.11 | 11/22/2021 |

| Exhibit No. | Description | Incorporation by Reference | | | |
|---|---|---|---|---|---|
| | | Form | File No. | Exhibit No. | Filing Date |
| 10.12† | Consultancy Agreement dated March 18, 2019, between Bionomics Limited and Adrian Hinton | F-1 | 333-261280 | 10.12 | 11/22/2021 |
| 10.13† | Letter, dated June 28, 2021, amending the Consultancy Agreement dated March 18, 2019, between Bionomics Limited and Adrian Hinton | F-1 | 333-261280 | 10.13 | 11/22/2021 |
| 10.14† | Letter, dated July 23, 2022, amending the Consultancy Agreement dated March 18, 2019, between Bionomics Limited and Adrian Hinton | 20-F | 001-41157 | 4.14 | 10/14/2022 |
| 10.15† | Letter of Appointment, dated September 3, 2008, between Bionomics Limited and Elizabeth Doolin | F-1 | 333-261280 | 10.14 | 11/22/2021 |
| 10.16† | Letter, dated July 1, 2020, from Bionomics Limited to Elizabeth Doolin | F-1 | 333-261280 | 10.15 | 11/22/2021 |
| 10.17† | Letter, dated July 1, 2021, from Bionomics Limited to Elizabeth Doolin | F-1 | 333-261280 | 10.16 | 11/22/2021 |
| 10.18† | Letter, dated July 1, 2022, from Bionomics Limited to Elizabeth Doolin | 20-F | 001-41157 | 4.18 | 10/14/2022 |
| 10.19† | Consultancy Agreement, dated April 1, 2021, between Bionomics Limited and Connor Bernstein | 20-F | 001-41157 | 4.19 | 10/14/2022 |
| 10.20† | Letter, dated July 27, 2022, amending Consultancy Agreement dated April 1, 2021, between Bionomics Limited and Connor Bernstein | 20-F | 001-41157 | 4.20 | 10/14/2022 |
| 10.21 | Subscription Agreement, dated June 1, 2020, by and between Bionomics Limited and Apeiron Investment Group Ltd | F-1 | 333-261280 | 10.17 | 11/22/2021 |
| 10.22 | Placement Agreement, dated November 9, 2018, by and between Bionomics Limited and BVF Partners L.P. | F-1 | 333-261280 | 10.18 | 11/22/2021 |
| 16.1 | Letter from Deloitte Touche Tohmatsu to the Securities and Exchange Commission, dated November 19, 2021 | F-1 | 333-261280 | 16.1 | 11/22/2021 |
| 21.1 | List of Subsidiaries of Bionomics Limited | F-1 | 333-261280 | 21.1 | 11/22/2021 |
| 23.1* | Consent of Ernst & Young, an independent registered public accounting firm. | | | | |
| 23.2** | Consent of Johnson Winter & Slattery (included in Exhibit 5.1) | | | | |
| 24.1* | Powers of Attorney (included on signature page to the registration statement) | | | | |
| 107* | Filing Fee Table | | | | |

* Filed herewith.
** To be filed by amendment.
† Indicates management contract or compensatory plan or arrangement.
# Portions of this exhibit (indicated by asterisks) have been omitted because the registrant has determined they are not material and would likely cause competitive harm to the registrant if publicly disclosed.

## SIGNATURES

Pursuant to the requirements of the Securities Act, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereto duly authorized in Boston, Massachusetts, on November 10, 2022.

**BIONOMICS LIMITED**

By: /s/ Errol De Souza, Ph.D.
Errol De Souza, Ph.D.
Executive Chairman

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Errol De Souza, Ph.D. and Adrian Hinton and each of them, individually, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead in any and all capacities, in connection with this registration statement, including to sign in the name and on behalf of the undersigned, this registration statement and any and all amendments thereto, including post-effective amendments and registrations filed pursuant to Rule 462 under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto such attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his substitute, may lawfully do or cause to be done by virtue hereof.

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities held on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| /s/ Errol De Souza, Ph.D.<br>Errol De Souza, Ph.D. | Executive Chairman (Principal Executive Officer) | November 10, 2022 |
| /s/ Adrian Hinton<br>Adrian Hinton | Acting Chief Financial Officer<br>(Principal Financial and Accounting Officer) | November 10, 2022 |
| /s/ Jane Ryan, Ph.D.<br>Jane Ryan, Ph.D. | Director | November 10, 2022 |
| /s/ Aaron Weaver<br>Aaron Weaver | Director | November 10, 2022 |
| /s/ David Wilson<br>David Wilson | Director | November 10, 2022 |
| /s/ Miles Davies<br>Miles Davies | Director | November 10, 2022 |
| /s/ Alan Fisher<br>Alan Fisher | Director | November 10, 2022 |

## SIGNATURE OF AUTHORIZED U.S. REPRESENTATIVE OF REGISTRANT

Pursuant to the requirements of the Securities Act of 1933, as amended, the undersigned, the duly authorized representative in the United States of Bionomics Limited has signed this registration statement on November 10, 2022.

**BIONOMICS LIMITED**

By: /s/ Errol De Souza, Ph.D.
Errol De Souza, Ph.D.
Executive Chairman

**Exhibit 23.1**

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption “Experts” in the Registration Statement (Form F-1) and related Prospectus of Bionomics Limited for the registration of American Depository Shares and to the incorporation by reference therein of our report dated October 14, 2022, with respect to the consolidated financial statements of Bionomics Limited included in its Annual Report (Form 20-F) for the year ended June 30, 2022, filed with the Securities and Exchange Commission.

Ernst & Young
Adelaide, Australia
November 10, 2022

**Calculation of Filing Fee Tables**

# Form F-1

(Form Type)

# Bionomics Limited

(Exact Name of Registrant as Specified in its Charter)

**Table 1: Newly Registered and Carry Forward Securities**

| | Security Type | Security Class Title | Fee Calculation or Carry Forward Rule | Amount Registered | Proposed Maximum Offering Price Per Unit | Maximum Aggregate Offering Price | Fee Rate | Amount of Registration Fee | Carry Forward Form Type | Carry Forward File Number | Carry Forward Initial effective date | Filing Fee Previously Paid In Connection with Unsold Securities to be Carried Forward |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Fees to Be Paid | Equity | Ordinary Shares, no par value(1) | Rule 457(c) | 611,702(2) | $9.40(3) | $5,749,998.80(3) | 0.00011020 | $633.65 | | | | |
| Fees Previously Paid | N/A | N/A | N/A | N/A | N/A | N/A | | N/A | | | | |
| Carry Forward Securities | | | | | | | | | | | | |
| Carry Forward Securities | N/A | N/A | N/A | N/A | | N/A | | | N/A | N/A | N/A | N/A |
| | **Total Offering Amounts** | | | | | $5,749,998.80(3) | | $633.65 | | | | |
| | **Total Fees Previously Paid** | | | | | | | N/A | | | | |
| | **Total Fee Offsets** | | | | | | | N/A | | | | |
| | **Net Fee Due** | | | | | | | $633.65 | | | | |

(1) American Depositary Shares (which we refer to as “ADSs”) issuable upon deposit of the ordinary shares registered hereby have been registered pursuant to a separate Registration Statement on Form F-6 (File No. 333-261582), which was declared effective on December 15, 2021. Each ADS represents 180 ordinary shares.

(2) Includes 91,755 ordinary shares represented by ADSs, which the underwriters have an option to purchase.

(3) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(c) under the Securities Act of 1933, as amended, based on the average of the high and low prices of shares of ADSs as reported on The Nasdaq Global Market on November 9, 2022.