

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

FORM 20-F

(Mark One) REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended June 30, 2022

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

OR

SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Date of event requiring this shell company report _____

Commission file number 001-41157

BIONOMICS LIMITED

(Exact name of Registrant as specified in its charter)

Not Applicable

(Translation of Registrant's name into English)

Australia

(Jurisdiction of incorporation or organization)

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Australia

(Address of principal executive offices)

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(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing the right to receive one hundred eighty (180) Ordinary Shares, no par value per share	BNOX	The Nasdaq Global Market

Securities registered or to be registered pursuant to Section 12(g) of the Act: None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

Indicate the number of outstanding shares of each of the issuer's classes of capital stock or common stock as of the close of business covered by the annual report. 1,353,350,744 ordinary shares.

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

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes No

Note—Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

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 13(a) of the Exchange Act.

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

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP

International Financial Reporting Standards as issued by the International Accounting Standards Board

Other

If "Other" has been checked in response to the previous question indicate by check mark which financial statement item the registrant has elected to follow. Item 17 Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

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GENERAL INFORMATION

Except where the context otherwise requires or where otherwise indicated, the terms “Bionomics,” the “Company,” “the Group,” “we,” “us,” “our,” “our company” and “our business” refer to Bionomics Limited, in each case together with its consolidated subsidiaries as a consolidated entity.

PRESENTATION OF FINANCIAL AND OTHER INFORMATION

We report under International Financial Reporting Standards (“IFRS”) as issued by the International Accounting Standards Board (“IASB”). None of our financial statements were prepared in accordance with generally accepted accounting principles in the United States (“U.S. GAAP”). We maintain our financial books and records and publish our consolidated financial statements in Australian Dollars, which is our functional and reporting currency.

Our financial information is presented in Australian Dollars. For the convenience of the reader, in this Annual Report, unless otherwise indicated, translations from Australian Dollars into U.S. dollars were made at the 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. Such U.S. dollar amounts are not necessarily indicative of the amounts of U.S. dollars that could actually have been purchased upon exchange of Australian Dollars at the dates indicated. All references in this Annual Report to “\$” mean U.S. dollars and all references to “A\$” mean Australian Dollars.

Certain figures included in this Annual Report and in our financial statements contained herein have been rounded for ease of presentation. Percentage and variance figures included in this Annual Report have in some cases been calculated on the basis of such figures prior to rounding. For this reason, certain percentage and variance amounts in this Annual Report may vary from those obtained by performing the same calculations using the figures in this Annual Report and in the consolidated financial statements contained herein. Additionally, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them.

MARKET AND INDUSTRY DATA

Unless otherwise indicated, information contained in this Annual Report 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.”

Industry publications and forecasts generally state that the information they contain has been obtained from sources believed to be reliable, but that the accuracy and completeness of such information is not guaranteed. Forecasts and other forward-looking information obtained from these sources are subject to the same qualifications and uncertainties as the other forward-looking statements in this Annual Report.

TRADEMARKS, SERVICE MARKS AND TRADE NAMES

We have proprietary rights to trademarks used in this Annual Report that are important to our business, many of which are registered under applicable intellectual property laws.

Solely for convenience, the trademarks, service marks, logos and trade names referred to in this Annual Report are without the ® and ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks and trade names. This Annual Report contains additional trademarks, service marks and trade names of others, which are the property of their respective owners. All trademarks, service marks and trade names appearing in this Annual Report are, to our knowledge, the property of their respective owners. We do not intend our use or display of other companies' trademarks, service marks, copyrights or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

AUSTRALIAN DISCLOSURE REQUIREMENTS

Our ordinary shares are publicly traded on the Australian Securities Exchange ("ASX") under the symbol "BNO". Our American Depositary Shares ("ADSs") each representing 180 of our ordinary shares are publicly traded on the Nasdaq Global Select Market, or Nasdaq under the symbol "BNOX". As part of our ASX listing, we are required to comply with various disclosure requirements as set out under the Australian Corporations Act 2001 (Cth) (the "Corporations Act") and the ASX Listing Rules. Information furnished under this sub-heading is intended to comply with the ASX Listing Rules and the Corporations Act disclosure requirements (if and to the extent that information has not been provided elsewhere this annual report).

ENFORCEMENT OF CIVIL LIABILITIES

We are a public limited company incorporated under the laws of Australia. Certain of our directors are non-residents of the United States and substantially all of their assets are located outside 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 our non-U.S. resident directors or on us;
- enforce in U.S. courts judgments obtained against our non-U.S. resident directors or us in the United States courts in any action, including actions under the civil liability provisions of U.S. securities laws;
- enforce in U.S. courts judgments obtained against our non-U.S. resident directors 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
- bring an original action in an Australian court to enforce liabilities against our non-U.S. resident directors or us based solely upon U.S. securities laws.

You may also have difficulties enforcing in courts outside the United States judgments that are obtained in U.S. courts against any of our non-U.S. resident directors or us, including actions under the civil liability provisions of the 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 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. The disclosure in this section is not based on the opinion of counsel.

We have appointed CSC-Lawyers Incorporating Service as our agent to receive service of process with respect to any action brought against us under the federal securities laws of the United States.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act, Section 21E of the Exchange Act, and the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, that are based on our management's beliefs and assumptions and on information currently available to our management. These forward-looking statements are contained principally in Item 3.D. "Risk Factors," Item 4. "Information on the Company" and Item 5. "Operating and Financial Review and Prospects." In some cases, you can identify forward-looking statements by the following words: "may," "might," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "seek," "believe," "estimate," "predict," "potential," "continue," "contemplate," "possible" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Statements regarding our future results of operations and financial position, growth strategy and plans and objectives of management for future operations are forward-looking statements.

Our estimates and forward-looking statements are mainly based on our current expectations and estimates of future events and trends which affect or may affect our business, operations and industry. Although we believe that these estimates and forward-looking statements are based upon reasonable assumptions, they are subject to numerous risks and uncertainties.

Many important factors could adversely impact our business and financial performance, including but not limited to those discussed in Item 3.D. "Risk Factors" of this Annual Report and the following:

- 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 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, needs for additional financing and the impact of a fluctuating currency exchange on these estimates;
- our financial performance;

- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;
- our anticipated use of our existing resources;
- cyber security risks and any failure to maintain the confidentiality, integrity and availability of our computer hardware, software and internet applications and related tools and functions;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act;
- 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; and
- other risks and uncertainties, including those listed under “Risk Factors.”

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 Annual Report and are subject to a number of risks, uncertainties and assumptions described under the sections in this Annual Report entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Annual Report. 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 Annual Report are excluded from the safe harbor protection provided by the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act.

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 Annual Report, 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.

PART I

Item 1. Identity of Directors, Senior Management and Advisers

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

A. [Reserved]

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Summary of Risk Factors

An investment in our American Depository Shares (“ADSs”) is subject to a number of risks, including risks related to our financial position and capital requirements, risks related to the discovery, development and regulatory approval of our product candidates, risks related to our reliance on third parties, risks related to commercialization of our product candidates, risks related to regulation of our industry, risks related to intellectual property, and risks related to ownership of our ADSs. Investors should carefully consider all of the information in this annual report before making an investment in the ADSs. The following list summarizes some, but not all, of these risks. Please read the information in the section entitled “Risk Factors” for a more thorough description of these and other risks.

Risks Related to our Financial Condition and Capital Requirements

- We have not received approval for any product candidate for commercial sale and, as a result, we have never generated any revenue, have incurred significant financial losses and expect to continue to incur significant financial losses in the future, which makes it difficult to assess our future viability.
- We will require additional capital in the future, which may not be available to us on commercially favorable terms, or at all. Raising additional capital may cause dilution to holders of our ADSs.

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

- Our preclinical and clinical programs may experience delays, unforeseen costs or may never advance, which would adversely affect our ability to obtain regulatory approvals or commercialize our product candidates.
- If we are not able to obtain 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.
- Changes in funding or disruptions within government agencies caused by funding shortages or global health concerns could prevent new or modified products from being developed, approved or commercialized.
- We may have difficulties in attracting and retaining key personnel, and if we fail to do so our business may suffer.

Risks Related to Our Reliance on Third Parties

- We rely on third-party manufacturers to produce current or any future product candidates. If such manufacturers do not produce acceptable product candidates, this could have a material adverse effect on our business.
- We are currently dependent on third parties to conduct clinical trials and some aspects of our research and development activities. Such third parties may not perform satisfactorily, including failing to meet deadlines for completion of such trial, research or testing.

Risks Related to Commercialization of Our Product Candidates

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

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, which could delay or prevent new products from being developed, approved or commercialized.
- We are subject to economic, political, regulatory and other risks associated with international operations.
- Changes in U.S. healthcare law may impact our business in ways that we cannot currently predict.

Risks Related to Our Intellectual Property

- If we are unable to obtain and maintain intellectual property protection for our products and technologies, or if we are unable to protect our intellectual property rights, we may not be able to compete effectively in our markets.
- We may become involved in lawsuits to protect or enforce our intellectual property, or third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights.
- Our current intellectual property portfolio may not prove to be sufficient to protect our competitive advantage. Additional competitors could enter the market, including with biosimilar products, and sales of affected products may decline materially.

Risks Related to Ownership of Our ADSs

- The rights of our shareholders may be different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions.
- 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.
- As a "foreign private issuer" in the U.S., 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.
- The dual listing of our ordinary shares and the ADSs may adversely affect the liquidity and value of the ADSs.

Implications of Being an Emerging Growth Company and a Foreign Private Issuer

Emerging Growth Company

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we may take advantage of specific exemptions from various reporting requirements that are applicable to other publicly traded entities that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (i.e., an auditor discussion and analysis);
- not being required to submit some executive compensation matters to shareholder advisory votes, such as "say-on-pay," "say-on-frequency" and "say-on-golden parachutes;" and
- not being required to disclose some executive compensation related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation.

As a result, we do not know if some investors will find our ADSs less attractive. The result may be a less active trading market for our ADSs, and the price of our ADSs may become more volatile.

We will remain an emerging growth company until the earliest of: (i) the last day of the first fiscal year in which our annual gross revenues exceed \$1.07 billion; (ii) the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering; (iii) the date that we become a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common equity held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter; or (iv) the date on which we have issued more than \$1 billion in non-convertible debt securities during any three-year period.

Foreign Private Issuer

We report under the Exchange Act as a non-U.S. company with foreign private issuer status. Even after we no longer qualify as an emerging growth company, as long as we qualify as a foreign private issuer under the Exchange Act, we will be exempt from specific provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specific information, or current reports on Form 8-K, upon the occurrence of specified significant events.

In addition, we will not be required to file annual reports and consolidated financial statements with the SEC as promptly as U.S. domestic companies whose securities are registered under the Exchange Act, and we will not be required to comply with Regulation FD, which restricts the selective disclosure of material information.

Both foreign private issuers and emerging growth companies also are exempt from some more stringent executive compensation disclosure rules. Thus, even if we no longer qualify as an emerging growth company, but remain a foreign private issuer, we will continue to be exempt from the more stringent compensation disclosures required of companies that are neither an emerging growth company nor a foreign private issuer.

RISK FACTORS

Investors should carefully consider the risks described below before making an investment decision. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations. Our business, financial condition or results of operations could be materially and adversely affected by any of these risks. The trading price and value of our ordinary shares could decline due to any of these risks, and investors may lose all or part of their investment. This Annual Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by us described below and elsewhere in this Annual Report.

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\$164.0 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 fail to 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.

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. Our existing capital will not be sufficient for us to fund our product candidates through regulatory approval, and we will need to raise additional capital to complete their development and commercialization.

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

We had cash and cash equivalents of A\$33.6 million (\$23.1 million) as of June 30, 2022. 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 our licensors and other third parties;
- the timing and amount of milestone or royalty payments we receive from out-licensees, such as Merck & Co., Inc., Kenilworth 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 holders of our ADSs, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial revenues, we expect to finance our business and operational needs through equity offerings, debt financings or other financing sources, including potentially collaborations, licenses and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, investors' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect investors' rights as a holder of our 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, development, regulatory approval and commercialization activities relating to our product candidates, which may change from time to time;
- the timing of milestone payments, if any, under our license and collaboration agreements;
- the timing and amount of royalty or other payments, if any, under our license and collaboration agreements;
- expenditures that we may incur to acquire, develop, or commercialize additional product candidates and technologies;
- the level of demand for our current or future product candidates, if approved, which may vary significantly;
- coverage and reimbursement policies with respect to our product candidates, if approved, and existing and potential future drugs that compete with our product candidates;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with third-party manufacturers;
- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation of our competitors or partners;
- the timing and exercise, if any, of outstanding 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 taxpayer must pass either the “continuity of ownership test” or, if it fails such test, the “business continuity test” in respect of relevant tax losses. We have not carried out any analysis as to whether we have met the continuity of ownership test or, failing such test, the business continuity test over relevant periods. In addition, shareholding changes may result in a significant ownership change for us under Australian tax law. It is therefore uncertain whether any of our losses carried forward as of June 30, 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 contract research organizations ("CROs"), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, contracting and training suitable clinical investigators;
- delays in obtaining required ethics committee or institutional review board, or 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 or failure in screening and enrolling suitable patients and delays or failure caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up, 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 or continuation of clinical trials;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;
- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization (“CMO”), and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and
- third parties being unwilling or unable to satisfy their contractual obligations to us.

Further, conducting clinical trials in foreign countries for our product candidates, 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 investors or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

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

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

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

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

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

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

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

commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

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

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

- regulatory authorities may suspend, withdraw or limit approvals of such current or future product candidates, or seek an injunction against their manufacture or distribution;
- regulatory authorities may require the addition of labeling statements or warnings, such as a “boxed” 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, 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 internal computer systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our drug development programs and other critical business functions.

Our internal computer systems and those of our third-party CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. 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. While we do not believe we have experienced any such 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.

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 Annual Report, and there can be no assurance that we will receive any such payments at all. We cannot be certain that any of the development and regulatory milestones will be achieved or that we will receive any future milestone payments under these agreements. In addition, in certain circumstances we may believe that we have achieved a particular milestone and the applicable collaboration partner may disagree with our belief. In that case, receipt of that milestone payment may be delayed or may never be received, which may require us to adjust our operating plans.

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

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

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

preserve our financial resources or to allow us adequate time to develop the required resources and systems and expertise ourselves.

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

We 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 ongoing Phase 2 SAD and PTSD clinical trials of BNC210, or 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;
- availability of alternative treatments already approved or expected to be commercially launched in the near future;
- the potential and perceived advantages of our current or future product candidates over current treatment options or alternative treatments, including future alternative treatments;
- the willingness of the target patient population to try new therapies or treatment methods and of physicians to prescribe these therapies or methods;

- the need to dose such product candidates in combination with other therapeutic agents, and related costs;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- our ability to obtain and maintain intellectual property protection;
- pricing and cost effectiveness;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness of our current or future product candidates;
- our ability to obtain sufficient third-party coverage or reimbursement; or
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

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

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

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

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

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

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

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

successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

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

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

There are currently no FDA-approved drugs for the acute treatment of SAD. There are 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 or fraudulent claim for purposes of the False Claims Act. Manufacturers can be held liable under the False Claims Act, even when they do not submit claims directly to government payors, if they are deemed to have “caused” the submission of the claim. The False Claims Act allows private individuals acting as “whistleblowers” to bring actions on the U.S. Federal Government’s behalf and to share in any recovery;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services information related to certain payments and other transfers of value to physicians (as defined by statute), certain non-physician practitioners (including nurse practitioners, certified nurse anesthetists, physician assistants, clinical nurse specialists, anesthesiology assistants and certified nurse midwives) as well as teaching hospitals. Manufacturers are also required to disclose ownership and investment interests held by physicians and their immediate family members;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers.

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

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

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

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

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

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

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

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

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

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

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

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate obligation to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of the Center for Medicare and Medicaid Innovation at the Centers for Medicare & Medicaid Services ("CMS") to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

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

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

- On August 2, 2011, the U.S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022. Under current legislation, the actual reduction in Medicare payments varies from 1% from April 1, 2022 through June 30, 2022, to up to 3% in the final fiscal year of this sequester, unless additional Congressional action is taken.
- On January 2, 2013, the U.S. American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers.
- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.
- On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.
- On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law, which, among other things, requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price

increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025).

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

The patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent position of pharmaceutical and biotechnology companies generally is highly uncertain and involves complex legal and factual questions for which many legal principles remain unresolved. Our pending and future patent applications may not result in patents being issued in the United States or in other jurisdictions which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. There is no assurance that all 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 Ownership of Our ADSs

The trading price of our ordinary shares has been volatile, and that of our ADSs may be volatile, and holders of our ADS may not be able to resell the ADSs at or above the price 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 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 Annual Report 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 may 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. We have 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.

Investors' right to participate in any future rights offering may be limited, which may cause dilution to holdings in our ADSs.

We may from time to time distribute rights to our shareholders, including rights to acquire our securities. However, we cannot make rights available to investors in the United States unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. Also, under the deposit agreement, the depositary bank will not make rights available to investors unless either both the rights and any related securities are registered under the Securities Act, or the distribution of them to ADS holders is exempted from registration under the Securities Act. 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. If the depositary does not distribute the rights, it may, under the deposit agreement, either sell them, if possible, or allow them to lapse. Accordingly, investors may be unable to participate in our rights offerings and may experience dilution in holdings in our ADSs.

Our executive officers, directors, principal shareholders and their affiliates will continue to exercise significant influence over our company, which will limit the ability of holders of our ADSs to influence corporate matters and could delay or prevent a change in corporate control.

Our executive officers, directors, principal shareholders and their affiliates represent, based on their ownership of our outstanding ordinary shares as of June 30, 2022 and beneficial ownership, in the aggregate, of approximately 32% of our outstanding ordinary shares, assuming no exercise of outstanding options and warrants to acquire additional ordinary shares. 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. 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.

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.

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 continue to be 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:

- we do not treat our ADS holders as one of our shareholders and they are not 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 our ADSs will be paid to the ADR depositary, and before the ADR depositary makes a distribution to ADS holders on behalf of their held 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, ADS holders 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.

ADS holders’ right 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 their holdings.

The deposit agreement provides that the depositary will not make rights available to ADS holders 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 depository 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 ADS holders will receive no value for these rights.

Investors may be subject to limitations on transfers of our ADSs and withdrawal of the underlying ordinary shares.

Our ADSs are transferable on the books of the depository. However, the depository 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 depository may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depository are closed, or at any time if we or the depository 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 the right to cancel held ADSs and withdraw the underlying ordinary shares. Temporary delays in the surrendering of our ADSs and withdrawal of the underlying ordinary shares may arise because the depository 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, ADS holders may not be able to cancel their ADSs and withdraw the underlying ordinary shares when they 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.

ADS holders must act through the ADR depository to exercise their voting rights and, as a result, may be unable to exercise voting rights on a timely basis.

We will not treat holders of our ADS (and not the ordinary shares underlying the ADSs) as one of our shareholders, and they will not be able to exercise shareholder rights directly. The ADR depository will be the holder of the ordinary shares underlying holders' 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 depository 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 depository 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 depository as to voting the ordinary shares represented by their ADSs. Due to these procedural steps involving the ADR depository, 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 depository 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 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. 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.

Holders of our ADSs 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 depository for the ADSs has agreed to pay 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. ADS holders will receive these dividends in proportion to the number of our ordinary shares such 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 holders of our ADSs 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. These restrictions may have a material adverse effect on the value of holders' 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 Annual Report. 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 initial public offering, (b) in which we have total annual gross revenue of at least \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our 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, it may be difficult 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*. 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” (as defined) 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. Holders of our ADSs 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 this Annual Report, prior to investing in the ADSs.

Holders of our ADSs 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 Annual Report 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 Annual Report and substantially all of our assets are located outside of the United States. As a result, it may not be possible or practicable 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 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.

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 if we cease to be an “emerging growth company” as defined in the JOBS Act, we continue to and will incur substantial legal, accounting and other expenses as a result of the reporting requirements of the Exchange Act. In addition, Sarbanes-Oxley Act, along with rules promulgated by the SEC, and Nasdaq, where our ADSs 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 have become more time-consuming and costly. For example, these regulations have made it more difficult to attract and retain qualified members of our board of directors and various corporate committees. Obtaining director and officer liability insurance is significantly more expensive as a public company.

If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our 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 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 Sarbanes-Oxley, our management will be required to report upon the 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 Annual Report, 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.

Item 4. Information on the Company

A. History and Development of the Company

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 Annual Report.

B. Business Overview

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 $\alpha 7$ nicotinic acetylcholine (“ACh”) receptor (“ $\alpha 7$ 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 $\alpha 7$ 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 $\alpha 7$ 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 $\alpha 7$ 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 topline data:

Program	Indication	Pre-Clinical	Phase 1	Phase 2	Phase 3	Status
BNC210 $\alpha 7$ receptor NAM	Social Anxiety Disorder (SAD)	PREVAIL				Study underway Topline Data: YE 2022
	Post-Traumatic Stress Disorder (PTSD)	ATTUNE				Study underway Topline Data: mid 2023

 FDA Fast Track designation

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

Program	Indication	Pre-Clinical	Phase 1	Phase 2	Phase 3	EXPECTED TIMING
EmpathBio BNC210	+MDMA derivative EMP-01 (PTSD)	MOU to explore combination treatment regimen			Feasibility assessment	
MERCK Collaboration α 7 receptor PAM	2 candidates for Cognitive Deficit in Alzheimer's	Phase 1 safety & biomarker studies ongoing				

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

α 7 Receptor PAM Program with Merck

In June 2014, we entered into the 2014 Merck License Agreement to develop α 7 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 $\alpha 7$ 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 $\alpha 7$ 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 $\alpha 7$ 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 $\alpha 7$ 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, $\alpha 7$ receptors. We have an ongoing collaboration with Merck for our $\alpha 7$ 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.

$\alpha 7$ Nicotinic Acetylcholine Receptor as a Target

The $\alpha 7$ 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 $\alpha 7$ receptor is unique because of its high calcium ion (Ca^{2+}) permeability and rapid desensitization. It is highly expressed in brain regions associated with cognitive performance, such as the basal forebrain, hippocampus and prefrontal cortex, as well as regions associated with emotional control, such as the amygdala and hippocampus. When the ACh neurotransmitter binds to the $\alpha 7$ 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 $\alpha 7$ 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).

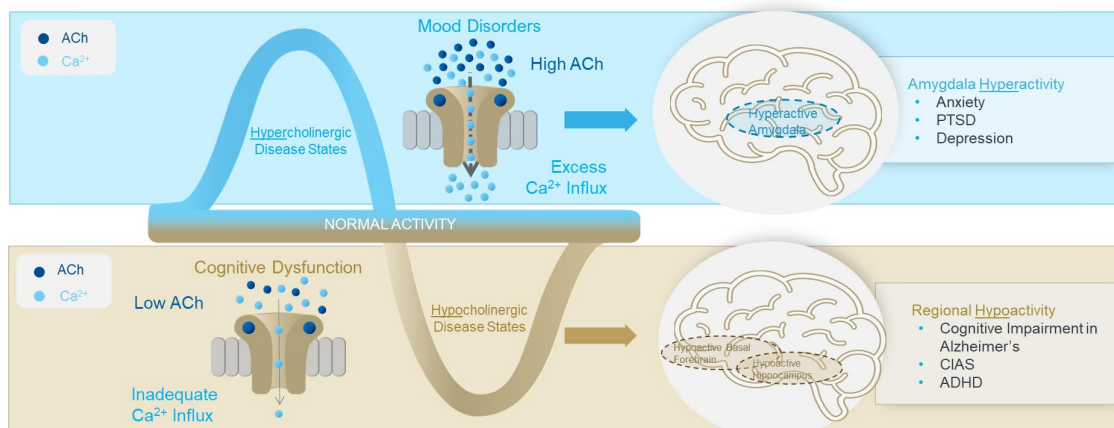


Figure 1: CNS conditions with acetylcholine imbalance at the $\alpha 7$ receptor.

Our Approach: Allosteric Modulation of the $\alpha 7$ Receptor and Clinical Biomarkers

We are focused on developing both NAMs and PAMs of the $\alpha 7$ 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 $\alpha 7$ 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 Ca^{2+} into the cell, which governs neuronal function and neurotransmission, as seen in the figure below.

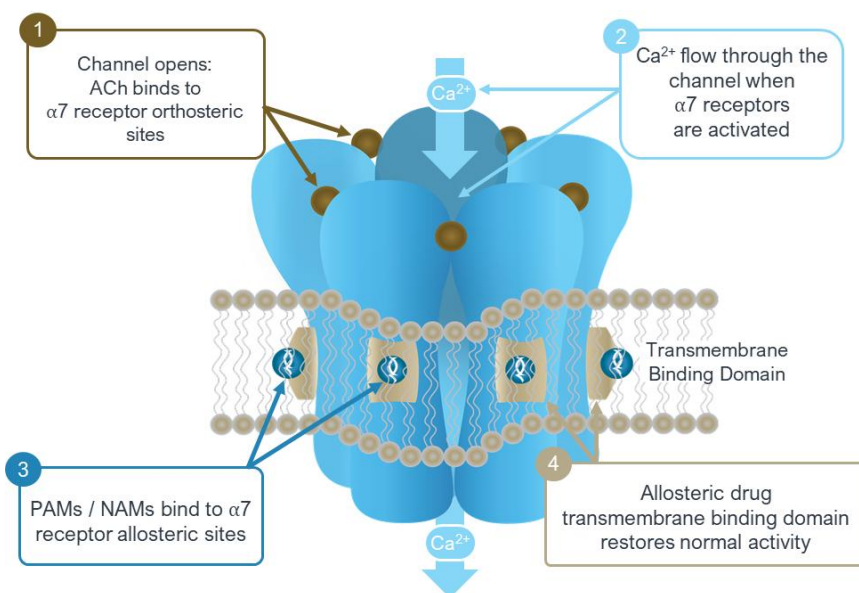


Figure 2: Structure of the $\alpha 7$ receptor showing the orthosteric and allosteric binding sites.

The $\alpha 7$ 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 $\alpha 7$ receptor have either targeted the orthosteric agonist sites or blocked the channel. These conventional orthosteric $\alpha 7$ 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 $\alpha 7$ 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 $\alpha 7$ 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 $\alpha 7$ 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 (“fMRI”), 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 $\alpha 7$ receptor and does not exert its effect on the $\alpha 7$ receptor unless in the presence of an agonist, such as ACh. When BNC210 binds to the $\alpha 7$ 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 $\alpha 7$ 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 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.

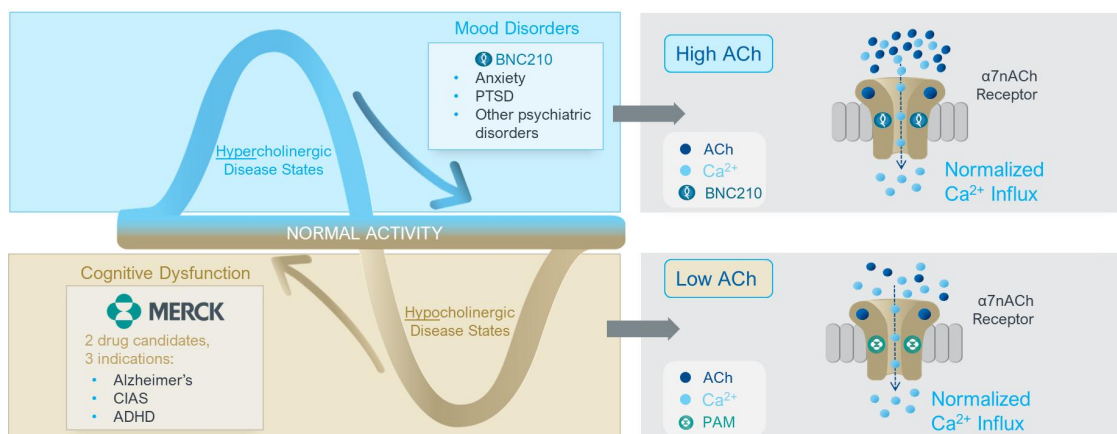


Figure 3. Action of BNC210 depends on ACh neurotransmission and allosteric modulation of $\alpha 7$ receptor.

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

- fast acting with the potential to be used in acute and chronic settings;
- non-sedating;
- no addictive effect and lack of discontinuation/withdrawal syndrome;
- no memory impairment; 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	✓	✗	✗	✗	✗
SSRIs / SNRIS ²	✗	✓	✗	✓	✓

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

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

* The number of enrolled subjects who were administered BNC210; other enrolled subjects were administered placebo 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 $\alpha 2$ EEG band, a measure of nicotine response in the brain. We observed a dose-dependent increase in power in the $\alpha 2$ EEG band following nicotine administration, which we believe is primarily attributable to the activation of two key nicotinic receptors: $\alpha 4\beta 2$ and $\alpha 7$. 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 $\alpha 2$ EEG band following nicotine administration, which we believe demonstrates target engagement and negative modulation of the $\alpha 7$ 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 $\alpha 4\beta 2$ nicotinic receptor, which BNC210 is not designed to engage.

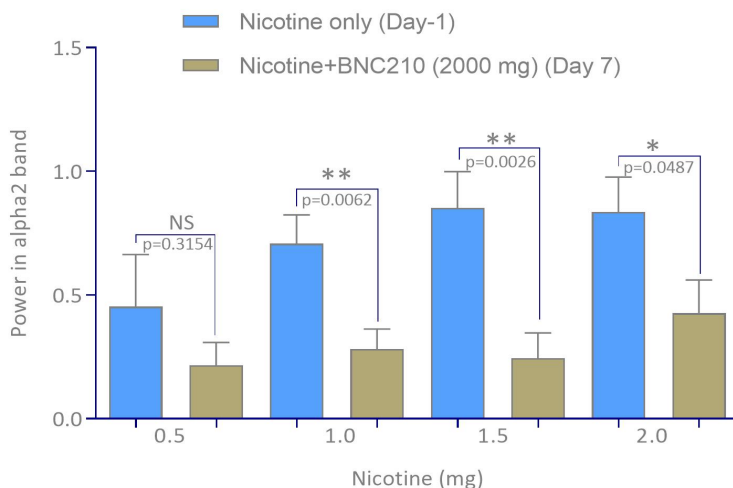


Figure 4: Demonstration of BNC210 brain penetration and target engagement of $\alpha 7$ receptor in humans.

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.

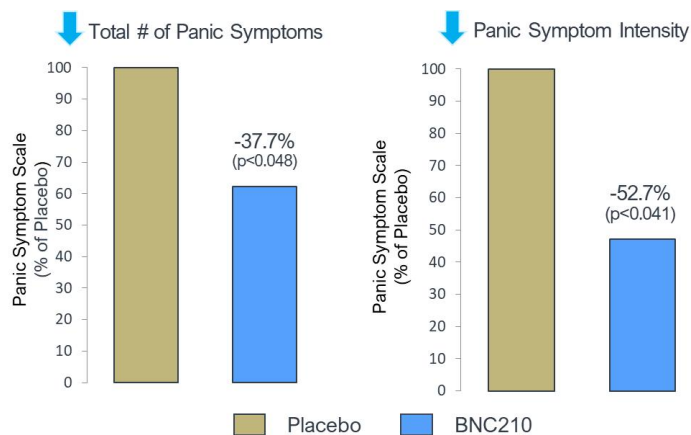


Figure 5: Results from BNC210 in a human CCK-4 challenge panic disorder.

We also conducted a Phase 2a randomized, double-blind, placebo-controlled, four-way crossover clinical trial in 24 newly diagnosed, treatment-naïve 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 ($p=0.003$).

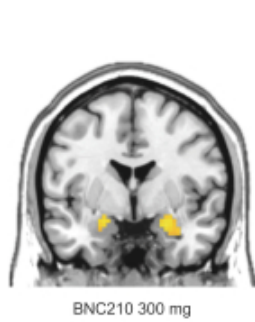


Figure 6: BNC210 300 mg significantly reduced activation of left and right amygdala while viewing fearful faces compared to placebo (L: $p=0.011$; R: $p=0.006$).

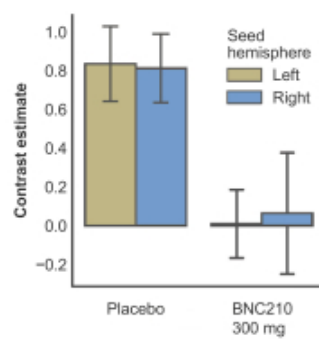


Figure 7: BNC210 300 mg significantly reduced connectivity between the amygdala and ACC while viewing fearful faces compared to placebo ($p=0.012$).

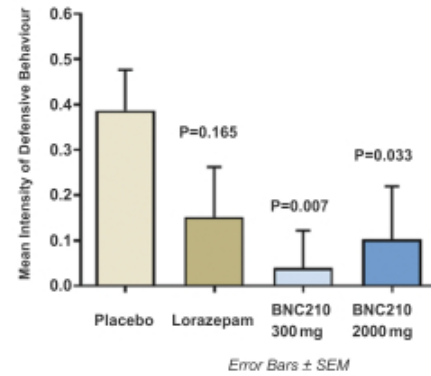


Figure 8: BNC210 significantly reduced threat avoidance behavior of anxious subjects in the JORT behavioral task compared to placebo.

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.

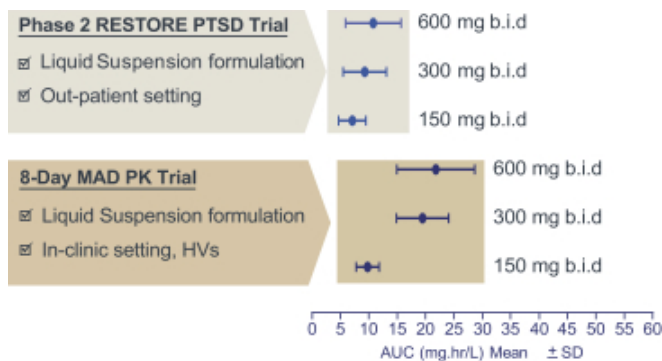


Figure 9: Out-patient Phase 2 PTSD RESTORE trial did not achieve exposure projected from in-clinic MAD study in healthy volunteers.

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.

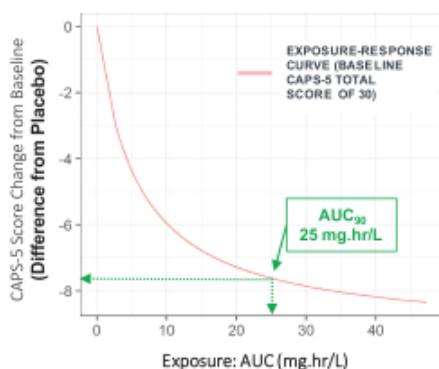


Figure 10: Pharmacometric model predicted BNC210 effect in a PTSD patient with a baseline CAPS-5 score of 30.

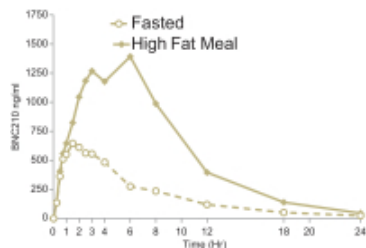
Novel, Proprietary Tablet Reformulation Effort

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 (“ t_{max} ”) 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

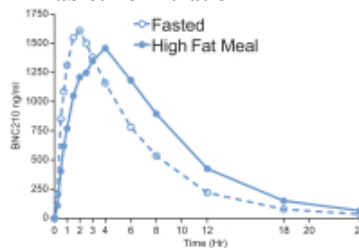


Figure 11: New tablet formulation overcomes food effect in healthy subjects.

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.

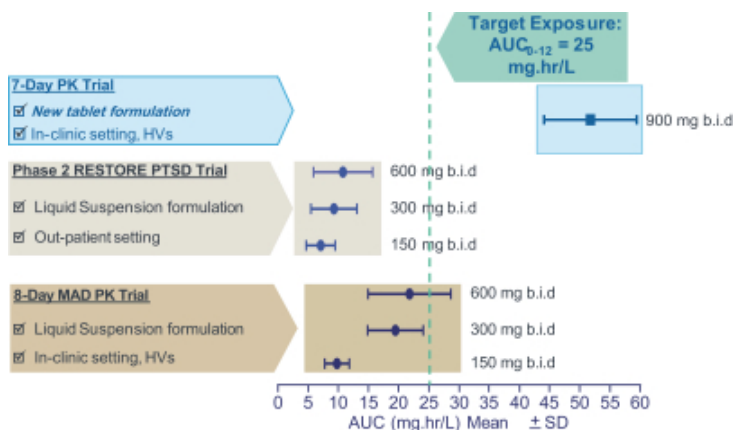


Figure 12: Pharmacokinetic (PK) study of tablet formulation in healthy volunteers achieved target exposure.

BNC210 Clinical Development in SAD

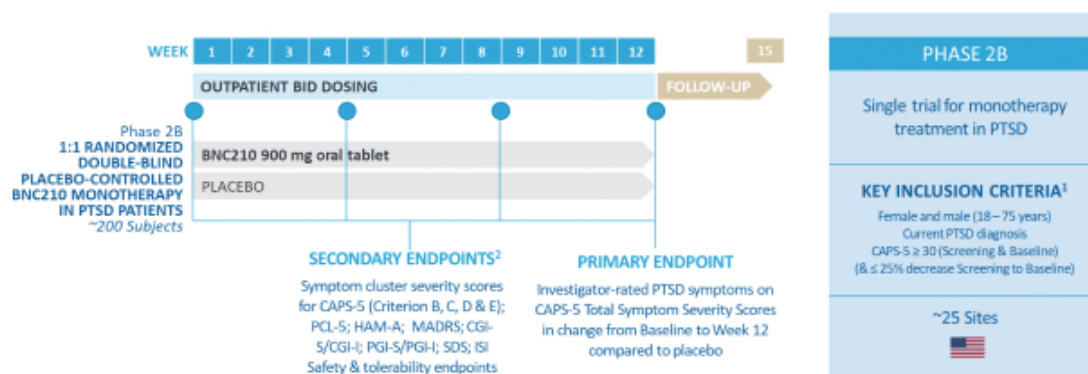
We have initiated an SAD trial, which we refer to as the PREVAIL Study, evaluating the effects of acute dosing of BNC210 on performance anxiety, using a standardized public speaking challenge. We are building on the favorable attributes of our novel tablet formulation with a rapid absorption profile 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 initiated our Phase 2 PREVAIL trial of BNC210 for the acute treatment of SAD, targeting 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 $\leq 25\%$ 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

$\alpha 7$ 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 $\alpha 7$ 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 $\alpha 7$ 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 $\alpha 7$ PAM discovery program which led to the identification of BNC375, a novel $\alpha 7$ PAM which is selective over related receptors and potentiates ACh-evoked $\alpha 7$ 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* ^{13}C -NMR analysis indicated that BNC375 treatment enhanced neurotransmitter release in rat medial prefrontal cortex. These findings suggest that $\alpha 7$ receptor PAMs may have multiple advantages over orthosteric $\alpha 7$ receptor agonists for the treatment of cognitive dysfunction associated with CNS diseases.

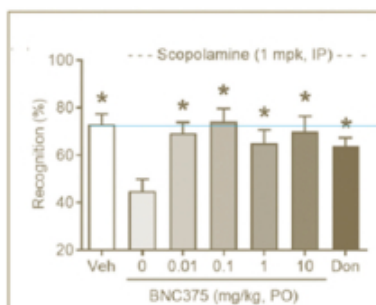


Figure 14: BNC375 in the Rat Novel Object Recognition memory test. Scopolamine is used to impair memory which is represented below the dotted Scopolamine line. Donepezil ("Don") (Aricept), a marketed drug for the treatment of cognitive impairment, is used as the positive control. BNC210 treatment was 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; * = $p < 0.05$.

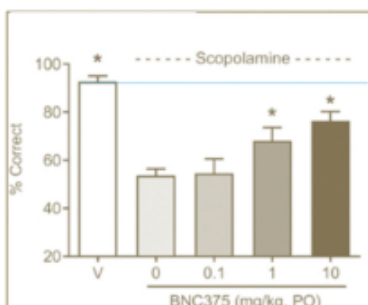


Figure 15: BNC375 in the Rhesus Object Retrieval Detour (ORD) memory test. Scopolamine was used to impair memory which is represented below the dotted Scopolamine line. BNC375 dose dependently reversed this impairment back towards the level of the control animals (blue line). V = 30% Captisol in water;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

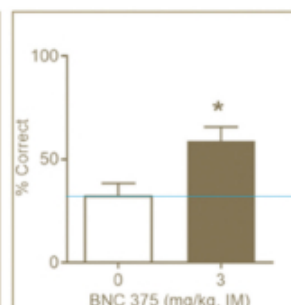


Figure 16: BNC375 statistically significantly reversed memory impairment (blue line) in African green monkeys in the ORD model. * = $p < 0.05$.

Our collaboration with Merck currently includes two candidates which are PAMs of the $\alpha 7$ 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 $\alpha 7$ 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 $\alpha 7$ 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 $\alpha 7$ 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 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 policies 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, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Further, in August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022. Under current legislation, the actual reduction in Medicare payments varies from 1% from April 1, 2022 through June 30, 2022, to up to 3% in the final fiscal year of this sequester, unless additional action is taken by Congress.

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

On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law, which marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (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, and while the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

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.

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

Data Privacy and Security Laws

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

Employees

As of June 30, 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.

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.

C. Organizational Structure

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 Annual Report.

Bionomics Limited is the parent company of two wholly-owned subsidiaries for which it holds 100% of the voting power: Bionomics Inc., incorporated in the United States on August 13, 2004, and Iliad Chemicals Pty Ltd, incorporated in Australia on December 21, 2001.

D. Property, Plant and Equipment

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 on 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.

Item 4A. Unresolved Staff Comments

None.

Item 5. Operating and Financial Review and Prospects

A. Operating Results

You should read the following discussion of our operating and financial review and prospects in conjunction with our consolidated financial statements and the related notes included elsewhere in this Annual Report. The following discussion is based on our financial information prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board.

This discussion contains forward-looking statements and involves numerous risks and uncertainties, including, but not limited to, those described in the "Risk Factors" section of this Annual Report. See "Cautionary Statement Regarding Forward-Looking Statements." Our actual results could differ materially from those contained in any forward-looking statements.

Certain information called for by this Item 5, including a discussion of the year ended June 30, 2020 compared to the year ended June 30, 2021 has been reported previously in our final prospectus filed pursuant to Rule 424(b)(4) on September 15, 2021 under the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations".

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 $\alpha 7$ nicotinic acetylcholine ("ACh") receptor (" $\alpha 7$ 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 $\alpha 7$ receptor to treat anxiety-related and cognitive disorders, respectively.

We are advancing our lead product candidate, BNC210, an oral proprietary selective NAM of the $\alpha 7$ 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 $\alpha 7$ 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 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\$173.3 million 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 our existing cash and cash equivalents will be sufficient to continue funding our development activities through to October 31, 2023. 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 materially 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 trials due 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 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 FDA, regulatory authorities in Europe, or other regulatory agencies, of the IND applications, clinical trial applications and/or other regulatory filings for BNC210, our other current product candidates and any future product candidates;

- expansion and maintenance of a workforce of experienced scientists and others to continue to develop our product candidates;
- successful application for and receipt of marketing approvals from applicable regulatory authorities;
- obtainment and maintenance of regulatory exclusivity for our product candidates;
- arrangements with third-party manufacturers for, or establishment of, commercial manufacturing capabilities;
- establishment of sales, marketing and distribution capabilities and successful launch of commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effective competition with other therapies;
- obtainment and maintenance of coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;
- obtainment, maintenance, enforcement, defense and protection of our rights in our intellectual property portfolio;
- avoidance of infringement, misappropriation or other violations with respect to others' intellectual property or proprietary rights; and
- maintenance of a continued acceptable safety profile of our products following receipt of any marketing approvals.

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

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

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)			
Continuing Operations	A\$	A\$	A\$	%
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	<u>(21,951)</u>	<u>(8,884)</u>	<u>13,067</u>	<u>148</u>

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

The increase of A\$4.5 million, or 344%, to A\$344 million in our other income for the fiscal year ended June 30, 2022 as compared to the fiscal year ended June 30, 2021 was due to an increase in government research and development incentives of A\$4.8 million as a result of an increase in qualifying research and development expenses for the Australian research and development credits, offset by a decrease in

sub-lease rent received of A\$0.2 million, as the sublease of our previous premises ceased on July 12, 2021 and 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.

Off-Balance Sheet Arrangements

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

JOBS Act

We are an emerging growth company, as defined in the JOBS Act. We rely on certain reduced reporting and other requirements that are otherwise generally applicable to public companies. As an emerging growth company, we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, which would otherwise be required beginning with our second annual report on Form 20-F, and (ii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis).

B. 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 full repaid during April 2021.

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 of A\$0.2 million relating to proceeds from disposals of plant and equipment.

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 our existing cash and cash equivalents will be sufficient to fund our current operations through to October 31, 2023. 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, 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.

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

C. Research and Development, Patents and Licenses, etc.

For a description of the amount spent during each of the last two fiscal years on company-sponsored research and development activities, as well as the components of research and development expenses, see “Item 5A-Operating Results - Results of Operations.”

For a description of our research and development process, see “Item 4B-Business Overview.”

D. Trend Information

Other than as disclosed elsewhere in this Annual Report, we are not aware of any trends, uncertainties, demands, commitments or events since June 30, 2022 that are reasonably likely to have a material adverse effect on our revenues, income, profitability, liquidity or capital resources, or that would cause the disclosed financial information to be not necessarily indicative of future operating results or financial conditions.

E. Critical Accounting 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

Certain new accounting standards and interpretations have been issued by the IASB, but are not yet effective for the June 30, 2022 reporting period and have not been early adopted by Bionomics and its subsidiaries. These standards are not expected to have a material impact on the entity in the current or future reporting periods nor on foreseeable future transactions.

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management Executive Officers and Board Members

The following table presents information about our current executive officers and board members, including their ages as of the date of this Annual Report:

Name	Age	Position
<i>Executive Officers</i>		
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
<i>Non-Employee Directors</i>		
Miles Davies	41	Director
Alan Fisher ⁽¹⁾ ⁽²⁾	69	Director
Jane Ryan, Ph.D. ⁽¹⁾ ⁽²⁾	63	Director
Aaron Weaver	41	Director
David Wilson ⁽¹⁾ ⁽²⁾	59	Director

⁽¹⁾ Audit and Risk Committee member

⁽²⁾ Nomination and Remuneration Committee member

Unless otherwise indicated, the current business addresses for our executive officers and the members of our board of directors is 200 Greenhill Road, Eastwood, South Australia, Australia.

Executive Officers

The following is a brief summary of the business experience of our 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 Bidel 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; Cycleron 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 Board Members

The following is a brief summary of the business experience of our non-employee board members.

Peter Miles Davies has served as a member of our board of directors since July 2021. 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 Anantara 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 Diversity

The table below provides certain information regarding the diversity of our board of directors as of the date of this Annual Report.

Board Diversity Matrix				
Country of Principal Executive Offices:	Australia			
Foreign Private Issuer	Yes			
Disclosure Prohibited under Home Country Law	No			
Total Number of Directors	6			
	Female	Male	Non-Binary	Did Not Disclose Gender
Part I: Gender Identity				
Directors	1	5	0	0
Part II: Demographic Background				
Underrepresented Individual in Home Country Jurisdiction	0			
LGBTQ+	0			
Did Not Disclose Demographic Background	1			

B. Compensation

We set out below the amount of compensation paid and benefits in kind provided by us or our subsidiaries to our executive officers and members of our board for services in all capacities to us or our subsidiaries for the fiscal year ended June 30, 2022, as well as the amount we contributed to retirement benefit plans for our executive officers and members of our board.

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. See the section titled "Executive Compensation" for more information.

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\$428,591 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, discretionary short-term performance incentives ("Discretionary STI Awards") may be awarded to our executives at the end of the performance review cycle upon achievement of specific board of directors approved individual and company-related key performance indicators ("KPIs"), with a weighting of 50% each. Following a performance evaluation against these KPIs, the amount of possible Discretionary STIs payable to each executive is determined by our board of directors based on the Executive Chair's recommendation. Our board of directors determines whether a Discretionary STI Award should be in share options, shares and/or cash.

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. 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 June 28, 2021, Mr. Hinton's fees payable under the Consultancy Agreement were changed to A\$20,000 (plus goods and services tax) per month for the period commencing July 1, 2021 until March 25, 2022, and extended to June 30, 2022, and the term of the agreement was extended through such date. The company subsequently agreed to extend the term of Mr. Hinton's Consultancy Agreement through June 30, 2022. 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, 2021, Ms. Doolin's salary was increased to A\$230,000 for the fiscal year ending June 30, 2022.

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, 2022. Under the agreement, Mr. Bernstein receives a consulting fee of \$15,000 per month. The Consultancy Agreement is subject to termination by either party on one 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 \$
<u>Dr. Errol De Souza</u>	<u>Executive Chairman</u>	<u>De Souza Target Bonus (60% of Base Salary)</u>	<u>100%</u>	<u>\$315,000</u>
		<u>IPO Options⁽ⁱ⁾</u>	-	<u>A\$1,311,119</u>
<u>Mr. Adrian Hinton</u>	<u>Acting Chief Financial Officer</u>	<u>Discretionary STI Award</u>	-	<u>A\$36,000</u>
		<u>Discretionary IPO Bonus</u>	-	<u>A\$40,000</u>
<u>Mr. Connor Bernstein</u>	<u>Vice President Strategy and Corporate Development</u>	<u>Discretionary STI Award</u>	-	<u>\$33,750</u>

<u>Ms. Liz Doolin</u>	<u>Vice President Clinical Development</u>	<u>Discretionary STI Award</u>	-	<u>A\$34,500</u>
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- (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 the financial statements.

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
<u>13,430,160</u>					<u>A\$1,311,119</u>

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
	<u>1,850,764</u>	<u>684,795</u>	<u>69,039</u>	<u>22,241</u>	<u>2,819,133</u>	<u>5,445,972</u>

(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 Award of 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 Bonus of \$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:

<u>Name</u>	<u>Number of Ordinary Share Options</u>	<u>Vesting Conditions</u>	<u>Exercise price</u>	<u>Expiration Date</u>
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
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, 1930
Dr. Errol De Souza	2,986,663 ⁽¹⁾	(2)	A\$0.2014	June 30, 1930
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 have been and are provided by a combination of equity plans that may 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 financial year to 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	<p><i>Ranking.</i> Shares issued under the A\$1,000 Plan rank equally with all our other fully paid ordinary shares at the time of issue.</p> <p><i>Dividends.</i> Holders of shares granted under the A\$1,000 Plan are entitled to participate in dividends declared and paid by us.</p> <p><i>Voting rights.</i> 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.</p> <p><i>New and bonus issues.</i> 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.</p>
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.
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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.
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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.

Dividends. Holders of shares granted under the EEP are entitled to participate in dividends declared and paid by us.

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, 2022 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.

C. Board Practices

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, we must hold an election of directors. The directors may appoint any eligible person to be a director, either as an addition to the existing directors or to fill a casual vacancy, but so that the total number of directors must not exceed the maximum number above, who holds office until the conclusion of the next annual general meeting following their appointment and is eligible for re-election. The Executive Chair, who in substance fulfils the role of Managing Director is not required to retire or stand for re-election. 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. If no director is required to retire under the casual vacancy or after the three year period, the directors who are required to retire are the directors longest in office since last being elected.

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 last re-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 our 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, Acting 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 Annual Report.

Corporate Governance Practices and Foreign Private Issuer Status

For information regarding our corporate governance practices and foreign private issuer status, see Item 16.G. “*Corporate Governance*.”

D. Employees

As of June 30, 2022, we had six full-time employees, one part-time employee, two full-time consultants and three part-time consultants. We have never experienced labor-related work stoppages or strikes and believe that our relations with our employees are satisfactory.

E. Share Ownership

For information regarding the share ownership of directors and officers, see Item 7.A. “*Major Shareholders and Related Party Transactions—Major Shareholders*.” For information as to our equity incentive plans, see Item 6.B. “*Compensation*.”

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table sets forth information known to us with respect to the beneficial ownership of our ordinary shares as of September 5, 2022, 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.

In preparing the disclosure below, we have relied to the extent we believe appropriate on substantial shareholder notices filed by our stockholders with the ASX. 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 September 5, 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 September 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.

Name of Beneficial Owner	Shares Beneficially Owned	
	Number	Percentage
5% or Greater Shareholders		
BVF Partners L.P. ⁽¹⁾	170,089,885	12.57%
Apeiron Investment Group Ltd ⁽²⁾	402,550,387	26.23%
Named Executive Officers and Directors		
Errol De Souza, Ph.D. ⁽³⁾	30,318,1688	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 4, 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 4, 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 4, 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 4, 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 4, 2022 or will become exercisable within 60 days of such date.

Significant Changes in Ownership

To our knowledge, other than as disclosed in the table above, our other filings with the SEC and this Annual Report, there has been no significant change in the percentage ownership held by any major shareholder during the past three years.

Voting Rights

Clause 7.10 of our Constitution stipulate the voting rights of members. In summary, but without prejudice to the provisions of the Constitution:

- on a show of hands, each member present has one vote; and
- on a poll every member present in person or by representative, proxy or attorney shall have one vote for each ordinary share held by the member.

Unlisted options and warrants carry no dividend or voting rights.

Change in Control Arrangements

We are not aware of any arrangement that may at a subsequent date, result in a change of control of the Company.

Registered Holders

Based on a review of the information provided to us by our transfer agent, as of September 5, 2022, there were 5,941 registered holders of our ordinary shares, one of which (Citicorp Nominees Pty Limited, the appointed custodian of the depository bank for our ADSs) is a United States registered holder, holding approximately 25.1% of our outstanding ordinary shares.

B. Related Party Transactions

The following is a summary of each transaction or series of similar transactions since July 1, 2021, 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.

Director and Senior Management Compensation

See "Item 6.B-Compensation" for information regarding compensation of our directors and senior management.

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 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.

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.

C. Interests of Experts and Counsel For the fiscal year ended June 30, 2022

Not applicable.

Item 8. Financial Information

A. Consolidated Statements and Other Financial Information

Consolidated Financial Statements

See Item 18. "Financial Statements."

Legal and Arbitration 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.

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.

In the fiscal year ended June 30, 2022, we did not declare or pay any dividends.

B. Significant Changes

None.

Item 9. The Offer and Listing

A. Offer and Listing Details

Our ordinary shares are publicly traded on the ASX, under the symbol "BNO". Our ADSs commenced trading on the Nasdaq Global Market on December 17, 2021 under the symbol "BNOX". Prior to this, no public market existed in the United States for our ADSs.

B. Plan of Distribution

Not applicable.

C. Markets

Our ordinary shares are publicly traded on the ASX, under the symbol "BNO". Our ADSs commenced trading on the Nasdaq Global Market on December 17, 2021 under the symbol "BNOX."

D. Selling Shareholders

Not Applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10. Additional Information

A. Share Capital

Not applicable.

B. Constitution

A copy of our constitution is attached as Exhibit 1.1 to this Annual Report. The information called for by this Item is set forth in Exhibit 2.3 to this Annual Report and is incorporated by reference into this Annual Report.

C. Material Contracts

Except as disclosed below or otherwise disclosed in this Annual Report (including the Exhibits), we are not currently, nor have we been for the past years immediately preceding the date of this Annual Report, party to any material contract, other than contracts entered into in the ordinary course of business.

D. Exchange Controls

Australia has largely abolished exchange controls on investment transactions. The Australian dollar is freely convertible into U.S. dollars or other currencies. In addition, there are currently no specific rules or limitations regarding the export from Australia of profits, dividends, capital or similar funds belonging to foreign investors, except that certain payments to non-residents must be reported to the Australian Transaction Reports and Analysis Centre ("AUSTRAC"), which monitors such transactions, and amounts on account of potential Australian tax liabilities may be required to be withheld unless a relevant taxation treaty can be shown to apply and under such there are either exemptions or limitations on the level of tax to be withheld.

E. Taxation

The following is a summary of material U.S. federal and Australian income tax considerations to U.S. Holders, 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 Annual Report, 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 as of the date hereof. 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.

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.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the informational requirements of the Exchange Act. Accordingly, we will be required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. The SEC maintains an internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

As a foreign private issuer, we are exempt under the Exchange Act from, among other things, the rules prescribing the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act 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. We are required to make certain filings with the SEC. The SEC maintains an internet website that contains reports, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that site is www.sec.gov.

I. Subsidiary Information

Not applicable.

Item 11. 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 increased as at June 30, 2022 mainly due to an increase in cash and cash equivalents that are denominated in U.S.-dollars as result of the U.S IPO.

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.

Item 12. Description of Securities Other than Equity Securities

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Citibank, N.A. as depository, registers and delivers American Depositary Shares, or ADSs. Each ADS represents one hundred eighty (180) ordinary shares (or a right to receive one hundred eighty (180) ordinary shares) deposited with Citicorp Nominees Pty Limited, as custodian for the depository in Australia. Each ADS also represents any other securities, cash or other property that may be held by the depository. The deposited shares together with any other securities, cash or other property held by the depository are referred to as the deposited securities. The depository's office at which the ADSs are administered and its principal executive office are located at 388 Greenwich Street, New York, New York 10013.

You may hold ADSs either (A) directly (i) by having an ADR, which is a certificate evidencing a specific number of ADSs, registered in your name, or (ii) by having uncertificated ADSs registered in your name, or (B) indirectly by holding a security entitlement in ADSs through your broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, or DTC. If you hold ADSs directly, you are a registered ADS holder, or an ADS holder. This description assumes you are an ADS holder. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to determine those procedures.

Registered holders of uncertificated ADSs receive statements from the depository confirming their holdings.

As an ADS holder, you are not treated as one of our shareholders and you do not have shareholder rights. Australian law governs shareholder rights. The depository is the holder of the shares underlying your ADSs. As a registered holder of ADSs, you have ADS holder rights. The amended and restated deposit agreement among us, the depository, ADS holders and all other persons indirectly or beneficially

holding ADSs sets out ADS holder rights as well as the rights and obligations of the depository. New York law governs the deposit agreement and the ADSs.

Fees and Charges

ADS holders will be required to pay the following fees under the terms of the deposit agreement:

Service	Fees
<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • ADS Services 	Up to U.S. 5¢ per ADS held on the applicable record date(s) established by the depository bank
<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • 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

ADS holders 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 depository 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 depository bank and/or service providers (which may be a division, branch or affiliate of the depository 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. Note that the fees and charges that may be required to be paid may vary over time and may be changed by us and by the depositary bank. ADS holders 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.

Taxes

ADS holders are 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. ADS holders 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 behalf of ADS holders. However, ADS holders 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. ADS holders 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 ADS holders.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

None.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

Use of Proceeds

In December 2021, we completed a U.S. initial public offering of 1,622,000 ADSs, each representing 180 ordinary shares, at an offering price of US\$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 initial public offering. 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. The offering commenced in December 2021 and did not terminate before all of the securities registered in the registration statement were sold. The effective date of the registration statement on Form F-1 (File No. 333-261280) for the offering was December 15, 2021.

Evercore ISI and William Blair acted as lead book-running managers for the offering. Cantor, Berenberg and H.C. Wainwright & Co. acted as book-running managers for the offering.

The net proceeds from our offering have been used, and are expected to continue to be used, as described in the final prospectus for the offering filed with the U.S. Securities and Exchange Commission on December 17, 2021.

Item 15. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as that term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended ("Exchange Act")) that are designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Executive Chairman and Acting Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Our management, with the participation of our Executive Chairman and Acting Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of June 30, 2022. Based upon that evaluation, our Executive Chairman and Acting Chief Financial Officer concluded that, as of June 30, 2022, our disclosure controls and procedures were effective to accomplish their objectives at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act) due to a transition period established by rules of the SEC for newly public companies. This Annual Report also does not include an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies. Additionally, our independent registered public accounting firm will not be required to opine on the effectiveness of our internal control over financial reporting until we are no longer an emerging growth company.

Changes in Internal Control over Financial Reporting

There were no changes in our internal controls over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act) that occurred during the period covered by

this Annual Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16A. Audit Committee Financial Expert

Our Board has determined that Mr. Alan Fisher, Mr. David Wilson and Dr. Jane Ryan each satisfy the “independence” requirements set forth in Rule 10A-3 under the Exchange Act. Our board of directors has also determined that Mr. Alan Fisher and Mr. David Wilson is considered an “audit committee financial expert” as defined in Item 16A of Form 20-F under the Exchange Act.

Item 16B. Code of Ethics

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 Chairman, Acting 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 annual report.

Item 16C. Principal Accounting Fees and Services

The consolidated financial statements of Bionomics at June 30, 2021 and 2022, and for each of the two years in the period ended June 30, 2022, appearing in this Annual Report have been audited by Ernst & Young, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing. The registered business address of Ernst & Young is 121 King William Street, Adelaide, South Australia 5000, Australia.

The table below sets out the total amount billed to us by Ernst & Young for services performed in the years ended June 30, 2021 and 2022, and breaks down these amounts by category of service:

	2022	2021
	\$'000	\$'000
Audit Fees	970	87
Audit Related Fees	-	-
Tax Fees	-	-
All Other Fees	-	-
Total	<u>970</u>	<u>87</u>

Audit Fees

Audit fees for the years ended June 30, 2021 and 2022 were related to the audit of our consolidated and subsidiary financial statements and other audit or interim review services provided in connection with statutory and regulatory filings or engagements.

Pre-Approval Policies and Procedures

The advance approval of the Audit Committee or members thereof, to whom approval authority has been delegated, is required for all audit and non-audit services provided by our auditors.

All services provided by our auditors are approved in advance by either the Audit Committee or members thereof, to whom authority has been delegated, in accordance with the Audit Committee's pre-approval policy.

Item 16D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 16F. Change in Registrant's Certifying Accountant

None.

Item 16G. Corporate Governance

As a "foreign private issuer," as defined by the SEC, we are permitted to follow home country corporate governance practices, instead of certain corporate governance practices required by Nasdaq for domestic issuers. While we voluntarily follow most Nasdaq corporate governance rules, we follow Australian corporate governance practices in lieu of Nasdaq corporate governance rules as follows:

- We 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 the ASX Corporate Governance Council Principles and Recommendations contain a non-binding recommendation that a majority of the board be comprised 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 Council Principles and Recommendations, which definition differs from Nasdaq's definition. Due to Australian law and generally accepted business practices in Australia regarding director independence, we have departed from this recommendation and differ to the independence requirements under the Nasdaq Listing Rules. Accordingly, we claim this exemption;
- We rely on an exemption from the requirement that all members of the compensation committee (known in Australia as a remuneration committee) and the nominating and corporate governance committees be independent as defined by Nasdaq. The ASX Corporate Governance Principles and Recommendations contain a non-binding recommendation that all ASX-listed companies should have a remuneration committee and a nominating committee comprised of at least three members, a majority of whom (including the chair) are independent. During the fiscal year ended June 30, 2022, a majority of the members of our remuneration committee and our nominating committee (including the respective chairs) were "independent" as defined in the ASX Corporate Governance Principles and Recommendations. Due to Australian law and generally accepted business practices in Australia regarding director independence, we have departed from this recommendation and differ to the independence requirements under the Nasdaq Listing Rules. Accordingly, we claim this exemption;
- We 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 claim this exemption;
- We rely on an exemption from the quorum requirements applicable to meetings of shareholders under the Nasdaq Listing Rules. In compliance with Australian law, our Constitution provides that five shareholders present holding not less than 5% of the issued capital of a company, 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 claim this exemption; and
- We rely on an exemption from the requirement prescribed by the 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% (or an additional 10% capacity to issue equity securities for the proceeding 12-month period if shareholder approval by special resolution is sought at our annual general meeting) of our issued share capital in any 12-month period (but, in determining the available 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 claim this exemption.

Although we may rely on certain home country corporate governance practices, we must comply with Nasdaq's Notification of Noncompliance requirement (Nasdaq Rule 5625) and the Voting Rights requirement (Nasdaq Rule 5640). Further, we must have an audit committee that satisfies Nasdaq Rule 5605(c)(3), which addresses audit committee responsibilities and authority and requires that the audit committee consist of members who meet the independence requirements of Nasdaq Rule 5605(c)(2)(A)(ii).

Other than as discussed above, we intend to comply with the rules generally applicable to U.S. domestic companies listed on Nasdaq. We may in the future, however, decide to use other foreign private issuer exemptions with respect to some or all of the other Nasdaq rules. Following our home country governance practices may provide less protection than is accorded to investors under Nasdaq rules applicable to domestic issuers.

We intend to take all actions necessary for us to maintain compliance as a foreign private issuer under the applicable corporate governance requirements of the Sarbanes-Oxley Act of 2002, the rules adopted by the SEC and Nasdaq listing standards.

Because we are a foreign private issuer, our directors and senior management are not subject to short-swing profit and insider trading reporting obligations under Section 16 of the Exchange Act. They will, however, be subject to the obligations to report changes in share ownership under Section 13 of the Exchange Act and related SEC rules.

Item 16H. Mine Safety Disclosure

Not applicable.

Item 16I. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 17. Financial Statements

We have provided financial statements pursuant to Item 18.

Item 18. Financial Statements

The audited consolidated financial statements as required under Item 18 are attached hereto starting on page F-1 of this Annual Report. The audit report of Ernst & Young, an independent registered public accounting firm, is included herein preceding the audited consolidated financial statements.

Item 19. Exhibits

List all exhibits filed as part of the registration statement or annual report, including exhibits incorporated by reference.

12		Incorporation by Reference				Filed / Furnished
Exhibit No.	Description	Form	File No.	Exhibit No.	Filing Date	
1.1	Constitution of Bionomics Limited adopted at the 2021 Annual General Meeting.	F-1/A	333-261280	3.1	12/08/2021	
2.1	Form of Depositary Agreement between Bionomics adopted at the 2021 Annual General Meeting	F-1/A	333-261280	4.1	12/13/2021	
2.2	Form of American Depositary Receipt evidencing American Depositary Shares (included in Exhibit 2.1)	F-1/A	333-261280	4.2	12/13/2021	
2.3	Description of Securities					*
4.1†	Bionomics Limited Employee Share Option Plan	F-1	333-261280	10.8	11/22/2021	
4.2†	Bionomics Limited Employee Share Plan (A\$1,000 Plan) – Terms of the Plan	F-1	333-261280	10.9	11/22/2021	
4.3†	Bionomics Limited Employee Equity Plan – Plan Rules	F-1	333-261280	10.10	11/22/2021	
4.4#	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	
4.5	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	
4.6#	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	
4.7#	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	
4.8#	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	
4.9#	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	
4.10	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	

Exhibit No.	Description	Form	File No.	Exhibit No.	Filing Date	Filed / Furnished
4.11†	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	
4.12†	Consultancy Agreement dated March 18, 2019, between Bionomics Limited and Adrian Hinton	F-1	333-261280	10.12	11/22/2021	
4.13†	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	
4.14†	Letter, dated July 23, 2022, amending the Consultancy Agreement dated March 18, 2019, between Bionomics Limited and Adrian Hinton					*
4.15†	Letter of Appointment, dated September 3, 2008, between Bionomics Limited and Elizabeth Doolin	F-1	333-261280	10.14	11/22/2021	
4.16†	Letter, dated July 1, 2020, from Bionomics Limited to Elizabeth Doolin	F-1	333-261280	10.15	11/22/2021	
4.17†	Letter, dated July 1, 2021, from Bionomics Limited to Elizabeth Doolin	F-1	333-261280	10.16	11/22/2021	
4.18†	Letter, dated July 1, 2022, from Bionomics Limited to Elizabeth Doolin					*
4.19†	Consultancy Agreement, dated April 1, 2021, between Bionomics Limited and Connor Bernstein					*
4.20†	Letter, dated July 27, 2022, amending Consultancy Agreement dated April 1, 2021, between Bionomics Limited and Connor Bernstein					*
8.1	List of Subsidiaries	F-1	333-261280	21.1	11/22/2021	
12.1	Certification of Principal Executive Officer (Errol De Souza) (136544746.1)					*
12.2	Principal Financial Officer Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*
13.1	Principal Executive Officer Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					**
13.2	Principal Financial Officer Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					**
15.1	Consent of Ernst & Young, an independent registered public accounting firm.					*
101.INS	Inline XBRL Instance Document.					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					*
101.DEF	Inline XBRL Taxonomy Definition Linkbase Document.					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					*
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)					*

* Filed herewith.

** Furnished herewith.

† 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.

Certain agreements filed as exhibits to this Annual Report contain representations and warranties that the parties thereto made to each other. These representations and warranties have been made solely for the benefit of the other parties to such agreements and may have been qualified by certain information that has been disclosed to the other parties to such agreements and that may not be reflected in such agreements. In addition, these representations and warranties may be intended as a way of allocating risks among parties if the statements contained therein prove to be incorrect, rather than as actual statements of fact. Accordingly, there can be no reliance on any such representations and warranties as characterizations of the actual state of facts. Moreover, information concerning the subject matter of any such representations and warranties may have changed since the date of such agreements.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

BIONOMICS LIMITED

Date: October 14, 2022

By: /s/ Errol De Souza, Ph.D.

Name: Errol De Souza, Ph.D.

Title: Executive Chairman

By: /s/ Adrian Hinton

Name: Adrian Hinton

Title: Acting Chief Financial Officer

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Bionomics Limited

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of Bionomics Limited (the Company) as of June 30, 2022 and 2021, and the related consolidated statements of profit or loss and other comprehensive income, changes in equity, and cash flows for each of the three years in the period ended June 30, 2022, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of June 30, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 2022, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ Ernst & Young

We have served as the Company's auditor since 2021.
Adelaide, Australia
October 14, 2022

Bionomics Limited
Consolidated Statement of Profit or Loss and Other Comprehensive Income
for the financial year ended June 30, 2022, 2021 and 2020

	Note	2022 A\$	2021 A\$	2020 A\$
Continuing Operations				
Revenue	5	263,634	-	46,662
Other income	5	5,808,231	1,308,343	3,312,753
Other (losses) and gains	5	(582,015)	4,272,931	4,575,881
Expenses				
Research and development expenses	6	(15,998,999)	(5,762,303)	(5,827,844)
Administration expenses		(7,398,476)	(4,372,823)	(3,670,647)
Occupancy expenses		(262,440)	(1,272,414)	(1,180,482)
Compliance expenses		(3,736,936)	(1,614,313)	(1,436,443)
Finance expenses		(44,165)	(1,443,885)	(1,846,467)
Loss before tax		<u>(21,951,166)</u>	<u>(8,884,464)</u>	<u>(6,026,587)</u>
Income tax benefit	7	191,808	187,427	207,612
Loss after tax from continuing operations		<u>(21,759,358)</u>	<u>(8,697,037)</u>	<u>(5,818,975)</u>
Discontinued Operations				
Loss for the year from discontinued operations	34(d)	-	-	(1,299,313)
Loss for the year		<u>(21,759,358)</u>	<u>(8,697,037)</u>	<u>(7,118,288)</u>
Other Comprehensive Income, Net of Income Tax				
Items that may be reclassified subsequently to profit or loss:				
Exchange differences on translating foreign operations		<u>1,067,134</u>	<u>(1,169,171)</u>	<u>530,915</u>
Total Comprehensive Loss for the Year		<u><u>(20,692,224)</u></u>	<u><u>(9,866,208)</u></u>	<u><u>(6,587,373)</u></u>
LOSS PER SHARE				
<i>From continuing operations</i>				
Basic loss per share	28	(A\$0.02) (2 cent)	(A\$0.01) (1 cent)	(A\$0.01) (1 cent)
Diluted loss per share	28	(A\$0.02) (2 cent)	(A\$0.01) (1 cent)	(A\$0.01) (1 cent)
<i>From discontinued operations</i>				
Basic loss per share	28	(A\$0.02) (2 cent)	(A\$0.01) (1 cent)	(A\$0.01) (1 cent)
Diluted loss per share	28	(A\$0.02) (2 cent)	(A\$0.01) (1 cent)	(A\$0.01) (1 cent)

The above Consolidated Statement of Profit or Loss and Other Comprehensive Income should be read in conjunction with the accompanying notes.

Bionomics Limited
Consolidated Statement of Financial Position
for the financial year ended June 30, 2022 and 2021

	Note	2022 A\$	2021 A\$
CURRENT ASSETS			
Cash and cash equivalents	8	33,564,857	28,499,449
Other financial assets	9	-	435,640
Trade and other receivables	10	64,360	200,212
Research and development incentives receivable		6,719,761	928,073
Other assets	11	1,461,268	863,630
TOTAL CURRENT ASSETS		<u>41,810,246</u>	<u>30,927,004</u>
NON-CURRENT ASSETS			
Property, plant and equipment	13	5,172	8,227
Right-to-use asset – rented property	14	669,358	862,716
Goodwill	15	12,868,122	12,400,743
Other intangible assets	16	9,838,274	9,945,755
Other financial assets	9	119,000	119,000
TOTAL NON-CURRENT ASSETS		<u>23,499,926</u>	<u>23,336,441</u>
TOTAL ASSETS		<u>65,310,172</u>	<u>54,263,445</u>
CURRENT LIABILITIES			
Trade and other payables	17	2,786,280	1,814,390
Borrowings	18	-	-
Lease liability – rented property	19	160,040	174,218
Provisions	20	409,320	371,936
TOTAL CURRENT LIABILITIES		<u>3,355,640</u>	<u>2,360,544</u>
NON-CURRENT LIABILITIES			
Borrowings	18	-	-
Lease liability – rented property	19	533,583	693,623
Provisions	20	10,460	6,782
Deferred tax liability	7(c)	1,798,625	1,842,303
Contingent consideration	30	2,699,010	1,762,656
TOTAL NON-CURRENT LIABILITIES		<u>5,041,678</u>	<u>4,305,364</u>
TOTAL LIABILITIES		<u>8,397,318</u>	<u>6,665,908</u>
NET ASSETS		<u>56,912,854</u>	<u>47,597,537</u>
EQUITY			
Issued capital	21	217,695,759	190,190,147
Reserves	22	12,523,598	11,447,891
Accumulated losses		(173,306,503)	(154,040,501)
TOTAL EQUITY		<u>56,912,854</u>	<u>47,597,537</u>

The above Consolidated Statement of Financial Position should be read in conjunction with the accompanying notes.

Bionomics Limited
Consolidated Statement of Changes in Equity
for the financial year ended June 30, 2022, 2021 and 2020

	Issued capital A\$	Foreign currency translation reserve A\$	Share-based payments reserve A\$	Accumulated losses A\$	Total Equity A\$
Balance at July 1, 2019	144,944,233	6,254,267	7,365,270	(142,064,706)	16,499,064
Loss for the period	-	-	-	(7,118,288)	(7,118,288)
Exchange differences on translation of foreign operations	-	530,915	-	-	530,915
Total comprehensive income	-	530,915.00	-	(7,118,288)	(6,587,373)
Recognition of share-based payments	-	-	55,355	-	55,355
Recycled on disposal of subsidiaries	-	(496,811)	-	-	(496,811)
Transfer of expired options	-	-	(295,212)	295,212	-
Issue of ordinary shares under a share placement	3,260,000	-	-	-	3,260,000
Share issue costs	(48,228)	-	-	-	(48,228)
Balance at June 30, 2020	148,156,005	6,288,371	7,125,413	(148,887,782)	12,682,007
Loss for the period	-	-	-	(8,697,037)	(8,697,037)
Exchange differences on translation of foreign operations	-	(1,169,171)	-	-	(1,169,171)
Total comprehensive income	-	(1,169,171)	-	(8,697,037)	(9,866,208)
Recognition of share-based payments	-	-	1,308,349	-	1,308,349
Transfer of expired options and warrants	-	-	(3,544,318)	3,544,318	-
Issue of ordinary shares under share placements	21,229,874	-	-	-	21,229,874
Issue of ordinary shares under rights issues	22,606,257	-	-	-	22,606,257
Issue of ordinary shares to employees	60,750	-	-	-	60,750
Share issue costs	(1,862,739)	-	1,439,247	-	(423,492)
Balance at June 30, 2021	190,190,147	5,119,200	6,328,691	(154,040,501)	47,597,537
Loss for the period	-	-	-	(21,759,358)	(21,759,358)
Exchange differences on translation of foreign operations	-	1,067,134	-	-	1,067,134
Total comprehensive income	-	1,067,134	-	(21,759,358)	(20,692,224)
Recognition of share-based payments	-	-	2,829,689	-	2,829,689
Transfer of expired options and warrants	-	-	(2,493,356)	2,493,356	-
Issue of ordinary shares as result of share options being exercised	27,200	-	-	-	27,200
Issue of ordinary shares as result of warrants being exercised	480,000	-	-	-	480,000
Transfer from share-based payments reserve	327,760	-	(327,760)	-	-
Issue of ordinary shares as result of US IPO	32,383,263	-	-	-	32,383,263
Share issue costs	(5,712,611)	-	-	-	(5,712,611)
Balance at June 30, 2022	217,695,759	6,186,334	6,337,264	(173,306,503)	56,912,854

The above Consolidated Statement of Changes in Equity should be read in conjunction with the accompanying notes.

Bionomics Limited
Consolidated Statement of Cash Flows
for the financial year ended June 30, 2022, 2021 and 2020

	Note	2022 A\$	2021 A\$	2020 A\$
Cash Flows from Operating Activities				
Research and development incentives received		-	2,919,541	7,482,764
Receipts from customers		270,975	394,815	4,883,858
Payments to suppliers and employees		(21,982,297)	(10,126,660)	(14,933,981)
Interest and bank fees paid		(44,165)	(726,420)	(1,335,834)
Net cash (used) by Operating Activities	27(b)	<u>(21,755,487)</u>	<u>(7,538,724)</u>	<u>(3,903,193)</u>
Cash Flows from Investing Activities				
Interest received		12,516	4,094	58,369
Payments for other financial assets		-	(118,466)	(52,174)
Proceeds from disposal of other financial assets		435,640	-	550,000
Payments for purchases of property, plant and equipment		(1,544)	(1,468)	(7,704)
Proceeds from disposals of property, plant and equipment		175,091	35,634	264,370
Net cash out flow from disposal of subsidiaries	34(c)	-	-	(1,007,992)
Net cash provided/(used) by Investing Activities		<u>621,703</u>	<u>(80,206)</u>	<u>(195,131)</u>
Cash Flows from Financing Activities				
Repayment of borrowings		-	(11,087,139)	(7,460,180)
Payments for transaction costs		-	-	(281,668)
Principal elements of lease payments		(174,218)	(779,807)	(826,942)
Proceeds from share issues		32,890,463	43,836,131	3,260,000
Payments for share issue costs		(5,720,623)	(415,479)	(48,228)
Net cash provided by Financing Activities		<u>26,995,622</u>	<u>31,553,706</u>	<u>(5,357,018)</u>
Net Increase in Cash and Cash Equivalents		5,861,838	23,934,776	(9,455,342)
Cash and cash equivalents at the beginning of the financial year		28,499,449	4,577,747	13,985,477
Effects of exchange rate changes on the balance of cash held in foreign currencies		(796,430)	(13,074)	47,612
Cash and Cash Equivalents at the End of the Year	27(a)	<u><u>33,564,857</u></u>	<u><u>28,499,449</u></u>	<u><u>4,577,747</u></u>

The above Consolidated Statement of Cash Flows should be read in conjunction with the accompanying notes.

Notes to the Financial Statements

for the financial year ended June 30, 2022, 2021 and 2020

NOTE 1: GENERAL INFORMATION

Bionomics Limited (“the Company”) is a listed public company incorporated in Australia. The address of its registered office and principal place of business is as follows:

200 Greenhill Road

Eastwood, South Australia, 5063

Tel: +61 8 8150 7400

Principal Activities

The principal activities of the Company and its controlled entities (“the Group”) during the period include the development of novel drug candidates focused on the treatment of serious central nervous system disorders.

NOTE 2: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

This financial report includes the consolidated financial statements and notes of the Group.

(i) Statement of Compliance

These financial statements comply with International Financial Reporting Standards (“IFRS”) as issued by the International Accounting Standards Board (“IASB”).

For the purposes of preparing the consolidated financial statements, the Company is a for-profit entity.

(ii) Basis of Preparation

The consolidated financial statements have been prepared on the basis of historical cost, except for certain non-current assets and financial instruments that are measured at fair values at the end of each reporting period, as explained in the accounting policies below. Historical cost is generally based on the fair values of the consideration given in exchange for assets. All amounts are presented in Australian dollars unless otherwise noted.

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, regardless of whether that price is directly observable or estimated using another valuation technique. In estimating the fair value of an asset or a liability, the Group takes into account the characteristics of the asset or liability if market participants would take those characteristics into account when pricing the asset or liability at measurement date. Fair value for measurement and/or disclosure purposes in these consolidated financial statements is determined on such a basis, except for share-based payment transactions that are within the scope of IFRS 2, leasing transactions that are within the scope of IFRS 16, and measurements that have some similarities to fair value but are not fair value, such as net realizable value in IFRS 2 or value in use in International Accounting Standards (“IAS”) 36.

In addition, for financial reporting purposes, fair value measurements are categorized into Level 1, 2 or 3 based on the degree to which inputs to the fair value measurements are observable market inputs and the significance of the inputs to the fair value measurement in its entirety, which are described as follows:

- Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the entity can access at measurement date;
- Level 2 inputs are inputs, other than quoted prices included within Level 1, that are observable for that asset or liability, either directly or indirectly, and
- Level 3 inputs are unobservable inputs for the asset or liability.

(iii) Application of New and Revised Accounting Standards

The Group has adopted all the new and revised Standards and Interpretations issued by the IASB that are relevant to its operations and effective for an accounting period that begins on or after July 1, 2021. The adoption of these new and revised Standards and Interpretations has resulted in no significant changes to the consolidated entity’s accounting policies. Standards and Interpretations issued by the IASB that are relevant to its operations from July 1, 2022 are not expected to result in significant changes to the consolidated entity’s accounting policies.

Notes to the Financial Statements

for the financial year ended June 30, 2022, 2021 and 2020

(iv) Accounting Policies

The following significant accounting policies have been adopted in the preparation and presentation of the financial report.

(a) Basis of Consolidation

The consolidated financial statements incorporate the financial statements of the Company and entities controlled by the Company and its subsidiaries. Control is achieved when the Company:

- has power over the investee;
- is exposed, or has rights, to variable returns from its involvement with the investee, and
- has the ability to use its power to affect its returns.

Consolidation of a subsidiary begins when the Company obtains control over the subsidiary and ceases when the Company loses control of the subsidiary. Specifically, income and expenses of a subsidiary acquired or disposed of during the year are included in the consolidated statement of profit or loss and other comprehensive income from the date the Company gains control until the date when the Company ceases to control the subsidiary.

When necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies into line with the Group's accounting policies.

All intragroup assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

(b) Borrowings

Borrowings are initially recognised at fair value, net of transaction costs incurred. Borrowings are subsequently measured at amortised cost. Any difference between the proceeds (net of transaction costs) and the redemption amount is recognised in profit or loss over the period of the borrowings using the effective interest method.

Borrowings are classified as current liabilities unless the Group has an unconditional right to defer settlement of the liability for at least 12 months after the balance sheet date.

(c) Borrowing Costs

All borrowing costs (other than transaction costs) are recognised in profit or loss in the period in which they are incurred. Borrowing costs consist of interest and other costs that an entity incurs in connection with the borrowing of funds.

(d) Business Combinations

Acquisitions of businesses are accounted for using the acquisition method. The consideration transferred in a business combination is measured at fair value which is calculated as the sum of the acquisition-date fair values of assets transferred by the Group, liabilities incurred by the Group to the former owners of the acquiree and the equity instruments issued by the Group in exchange for control of the acquiree. Acquisition-related costs are recognised in profit or loss as incurred.

At the acquisition date, the identifiable assets acquired, and the liabilities assumed are recognised at their fair value, except that:

- Deferred tax assets or liabilities, and assets or liabilities related to employee benefit arrangements, are recognised and measured in accordance with IAS 12 'Income Taxes' and IAS 19 'Employee Benefits', respectively;
- Liabilities or equity instruments related to share-based payment arrangements of the acquiree, or share-based payment arrangements of the Group entered into to replace share-based payment arrangements of the acquiree are measured in accordance with IFRS 2 'Share-based Payment' at the acquisition date, and
- Assets (or disposal groups) that are classified as held for sale in accordance with IFRS 5 'Non-current Assets Held for Sale and Discontinued Operations' are measured in accordance with that Standard.

Notes to the Financial Statements

for the financial year ended June 30, 2022, 2021 and 2020

Goodwill is measured as the excess of the sum of the consideration transferred, the amount of any non-controlling interests in the acquiree, and the fair value of the acquirer's previously held equity interest in the acquiree (if any) over the net of the acquisition-date amounts of the identifiable assets acquired and the liabilities assumed. If, after reassessment, the net of the acquisition-date amounts of the identifiable assets acquired and liabilities assumed exceeds the sum of the consideration transferred, the amount of any non-controlling interests in the acquiree and the fair value of the acquirer's previously held interest in the acquiree (if any), the excess is recognised immediately in profit or loss as a gain on bargain purchase.

Where the consideration transferred by the Group in a business combination includes assets or liabilities resulting from a contingent consideration arrangement, the contingent consideration is measured at its acquisition-date fair value. Changes in the fair value of the contingent consideration that qualify as measurement period adjustments are adjusted retrospectively, with corresponding adjustments against goodwill. Measurement period adjustments are adjustments that arise from additional information obtained during the 'measurement period' (which cannot exceed one year from the acquisition date) about facts and circumstances that existed at the acquisition date.

The subsequent accounting for changes in the fair value of contingent consideration that do not qualify as measurement period adjustments depends on how the contingent consideration is classified. Contingent consideration that is classified as equity is not remeasured at subsequent reporting dates and its subsequent settlement is accounted for within equity. Contingent consideration is recognised at fair value, classified as a liability which is remeasured at subsequent reporting dates in accordance with IFRS 9 and IAS 137 'Provisions, Contingent Liabilities and Contingent Assets' respectively, as appropriate, with the corresponding gain or loss being recognised in profit or loss.

If the initial accounting for a business combination is incomplete by the end of the reporting period in which the combination occurs, the Group reports provisional amounts for the items for which the accounting is incomplete. Those provisional amounts are adjusted during the measurement period (see above), or additional assets or liabilities are recognised, to reflect new information obtained about facts and circumstances that existed as of the acquisition date that, if known, would have affected the amounts recognised as of that date.

(e) Cash and Cash Equivalents

Cash and cash equivalents include cash on hand, deposits held at call with financial institutions, other short term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value and bank overdrafts. Bank overdrafts are shown within borrowings in current liabilities on the consolidated statement of financial position.

(f) Earnings/(Loss) per Share

- *Basic Earnings/(Loss) per Share*
Basic earnings/(loss) per share is calculated by dividing the profit/(loss) after income tax attributable to equity holders of the Company, excluding any costs of servicing equity other than ordinary shares, by the weighted average number of ordinary shares outstanding during the year, adjusted for bonus elements in ordinary shares issued during the year.
- *Diluted Earnings/(Loss) per Share*
Diluted earnings/(loss) per share adjusts the figures used in the determination of basic earnings per share to take into account the after income tax effect of interest and other financing costs associated with dilutive potential ordinary shares and the weighted average number of shares assumed to have been issued for no consideration in relation to options.

(g) Employee Benefits

- *Short-term and Long-term Employee Benefits*
A liability is recognised for benefits accruing to employees in respect of wages and salaries, annual leave and long service leave when it is probable that settlement will be required, and they are capable of being measured reliably. Liabilities recognised in respect of short-term employee benefits, are measured at their nominal values using the remuneration rate expected to apply at the time of settlement. Liabilities recognised in respect of long-term employee benefits are measured as the present value of the estimated

Notes to the Financial Statements

for the financial year ended June 30, 2022, 2021 and 2020

future cash outflows to be made by the Group in respect of services provided by employees up to reporting date, discounted using rates applicable to high quality corporate bonds.

- **Superannuation**
Retirement benefits are contributions made to employee superannuation funds and are charged as expenses when incurred. These contributions are made to external superannuation funds and are not defined benefits programs.
- **Share-based Payments**
Share-based compensation benefits have been provided to employees via the Bionomics Employee Equity Plan ("EEP"), with the exception of share options issued to the Executive Chairman which were approved by shareholders at the Annual General Meeting held on December 2, 2021.

The fair value of shares issued to employees for no cash consideration under the EEP and share options issued to the Executive Chairman are recognised as an employee benefits expense with a corresponding increase in equity. The fair value is measured at grant date and recognised on a straight-line basis over the vesting period based on the Group's estimate of equity instruments that will eventually vest or over the period of the Consultancy Agreement, as applicable.

The disclosure in Note 21 relates to the EEP and the former Employee Share Option Plan ("ESOP"). The Bionomics EEP was approved by the Board and shareholders in 2017. Staff eligible to participate in the plan are those who have been a full-time or part-time employee of the Group for a period of not less than six months or a Director of the Group. Options are granted under the plan for no consideration and vest equally over five years, or when vesting conditions are achieved, unless they are bonus options which vest immediately. The amounts disclosed as remuneration relating to options are the assessed fair values at grant date of those options allocated equally over the period from grant date to vesting date. See Note 21 for details on how the fair value of options and warrants issued during the year are calculated.

(h) Financial Assets

All regular way purchases or sales of financial assets are recognised and derecognized on a trade date basis. Regular way purchases or sales are purchases or sales of financial assets that require delivery of assets within the time frame established by regulation or convention in the marketplace.

All recognised financial assets are measured subsequently in their entirety at either amortised cost or fair value, depending on the classification of the financial assets.

Classification of Financial Assets at amortised costs

- The financial asset is held within a business model whose objective is to hold financial assets in order to collect contractual cash flow, and
- The contractual terms of the financial asset give rise on specified dates to cash flows that are solely payment of principal and interest on the principal amount outstanding.

Debt instruments that meet the following conditions are measured subsequently at fair value through other comprehensive income ("FVTOCI"):

- The financial asset is held within a business model whose objective is achieved by both collecting contractual cash flows and selling the financial assets, and
- The contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

By default, all other financial assets are measured subsequently at fair value through profit or loss ("FVTPL").

Despite the foregoing, the Group may make the following irrevocable election/designation at initial recognition of a financial asset:

- The Group may irrevocably elect to present subsequent changes in fair value of an equity investment in other comprehensive income if certain criteria are met (see (ii) below); and

Notes to the Financial Statements

for the financial year ended June 30, 2022, 2021 and 2020

- The Group may irrevocably designate a debt investment that meets the amortised cost or FVTOCI criteria as measured at FVTPL if doing so eliminates or significantly reduces an accounting mismatch (see (ii) below).

(i) *Amortised Cost and Effective Interest Method*

The effective interest method is a method of calculating the amortised cost of a debt instrument and of allocation interest income over the relevant period.

For financial assets other than purchased or originated credit-impaired financial assets (i.e. assets that are credit-impaired on initial recognition), the effective interest rate is the rate that exactly discounts estimated future cash receipts (including all fees and points paid or received that form an integral part of the effective interest rate, transaction costs and other premiums or discounts) excluding expected credit losses, through the expected life of the debt instrument, or, where appropriate, a shorter period, to the gross carrying amount of the debt instrument on initial recognition. For purchased or originated credit-impaired financial assets, a credit-adjusted effective interest rate is calculated by discounting the estimated future cash flows, including expected credit losses, to the amortised cost of the debt instrument on initial recognition.

The amortised cost of a financial asset is the amount at which the financial asset is measured at initial recognition minus the principal repayments, plus the cumulative amortisation using the effective interest method of any difference between that initial amount and the maturity amount, adjusted for any loss allowance.

The gross carrying amount of a financial asset is the amortised cost of a financial asset before adjusting for any loss allowance.

Interest income is recognised using the effective interest method for debt instruments measured subsequently at amortised cost and at FVTOCI. For financial assets other than purchased or originated credit-impaired financial assets, interest income is calculated by applying the effective interest rate to the gross carrying amount of a financial asset, except for financial assets that have subsequently become credit-impaired, (see below). For financial assets that have subsequently become credit-impaired, interest income is recognised by applying the effective interest rate to the amortised cost of the financial asset. If, in subsequent reporting periods, the credit risk on the credit-impaired financial instrument improves so that the financial asset is no longer credit-impaired, interest income is recognised by applying the effective interest rate to the gross carrying amount of the financial asset.

For purchased or originated credit-impaired financial assets, the Group recognizes interest income by applying the credit-adjusted effective interest rate to the amortised cost of the financial asset from initial recognition. The calculation does not revert to the gross basis even if the credit risk of the financial asset subsequently improves so that the financial asset is no longer credit-impaired.

Interest income is recognised in profit or loss and is included in the “other Scholes model was used to obtain income” line item.

(ii) *Financial Assets at FVTPL*

Financial assets that do not meet the criteria for being measured at amortised cost or FVTOCI are measured at FVTPL. Specifically:

- Investments in equity instruments are classified as at FVTPL, unless the Group designates an equity investment that is neither held for trading nor a contingent consideration arising from a business combination as at FVTOCI on initial recognition.
- Debt instruments that do not meet the amortised cost criteria or the FVTOCI criteria are classified as at FVTPL. In addition, debt instruments that meet either the amortised cost criteria or the FVTOCI criteria may be designated as at FVTPL upon initial recognition if such designation eliminates or significantly reduces a measurement or recognition inconsistency (so called ‘accounting mismatch’) that would arise from measuring assets or liabilities or recognizing the gains and losses on them on different bases. The Group has not designated any debt instructions as at FVTPL.

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Financial assets at FVTPL are measured at fair value at the end of each reporting period, with any fair values gains or losses recognised in profit or loss to the extent they are not part of a designated hedging relationship (see hedge accounting policy). The net gain or loss recognised in profit or loss includes any dividend or interest earned on the financial asset and is included in the 'other gains and losses' line item.

(iii) *Impairment of Financial Assets*

The Group recognizes a loss allowance for expected credit losses ("ECL") on investments in debt instruments that are measured at amortised cost or a FVTOCI, lease receivables, trade receivables and contract assets, as well as on financial guaranteed contracts. The amount of expected credit losses is updated at each reporting date to reflect changes in credit risk since initial recognition of the respective financial instrument.

The Group always recognizes lifetime ECL for trade receivables, contract assets and lease receivables. The expected credit losses on these financial assets are estimated using a provision matrix based on the Group's historical credit loss experience, adjusted for factors that are specific to the debtors, general economic conditions and an assessment of both the current as well as the forecast direction of conditions at the reporting date, including time value of money where appropriate.

For all other financial instruments, the Group recognizes lifetime ECL when there has been a significant increase in credit risk since initial recognition. However, if the credit risk on the financial instrument has not increased significantly since initial recognition, the Group measures the loss allowance for that financial instrument at an amount equal to 12-month ECL.

Lifetime ECL represents the expected credit losses that will result from all possible default events over the expected life of a financial instrument. In contrast, 12-month ECL represents the portion of lifetime ECL that is expected to result from default events on a financial instrument that are possible within 12 months after the reporting date.

(i) **Foreign Currencies**

The individual financial statements of each group entity are presented in the currency of the primary economic environment in which the entity operates (its functional currency). For the purpose of the consolidated financial statements, the results and financial position of each group entity are expressed in Australian dollars ("A\$"), which is the functional currency of the Company and the presentation currency for the consolidated financial statements.

In preparing the financial statements of each individual group entity, transactions in currencies other than the entity's functional currency (foreign currencies) are recognised at the rates of exchange prevailing at the dates of the transactions. At the end of each reporting period, monetary items denominated in foreign currencies are retranslated at the rates prevailing at that date. Non-monetary items carried at fair value that are denominated in foreign currencies are retranslated at the rates prevailing at the date when the fair value was determined. Non-monetary items that are measured in terms of historical cost in a foreign currency are not retranslated.

Exchange differences on monetary items are recognised in profit or loss in the period in which they arise except for exchange differences on monetary items receivable from or payable to a foreign operation for which settlement is neither planned nor likely to occur (therefore forming part of the net investment in the net investment in the foreign operation), which are recognised initially in other comprehensive income and reclassified from equity to profit or loss on repayment of the monetary items.

For the purpose of presenting these consolidated financial statements, the assets and liabilities of the Group's foreign operations are translated into Australian dollars using exchange rates prevailing at the end of the reporting period. Income and expense items are translated at the average exchange rates for the period. Exchange differences arising, if any, are recognised in other comprehensive income and accumulated in equity.

Goodwill and fair value adjustments to identifiable assets acquired and liabilities assumed through acquisition of a foreign operation are treated as assets and liabilities of the foreign operation and translated at the rate of

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exchange prevailing at the end of each reporting period. Exchange differences arising are recognised in other comprehensive income and accumulated in equity.

(j) Goods and Services Tax (“GST”)

Revenues, expenses and assets are recognised net of the amount of associated GST, unless the GST incurred is not recoverable from the taxation authority. In this case it is recognised as part of the cost of acquisition of the asset or as part of the expense.

Receivables and payables are stated inclusive of the amount of GST receivable or payable. The net amount of GST recoverable from, or payable to, the taxation authority is included with other receivables or payables in the consolidated statement of financial position.

Cash flows are presented on a gross basis. The GST component of cash flow arising from investing or financing activities which are recoverable from, or payable to the taxation authority, are presented as operating cash flow.

(k) Government Research and Development Incentives

Government grants, including Research and Development incentives, are recognised at fair value where there is reasonable assurance that the grant will be received, and all grant conditions will be met.

Grants relating to cost reimbursements are recognised as other income in profit or loss in the period when the costs were incurred or when the incentive meets the recognition requirements (if later).

(l) Impairment of Tangible and Intangible Assets Other than Goodwill

At the end of each reporting period, the Group reviews the carrying amounts of its tangible and intangible assets to determine whether there is any indication that those assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss (if any). When it is not possible to estimate the recoverable amount of an individual asset, the Group estimates the recoverable amount of the cash generating unit (“CGU”) to which the asset belongs. When a reasonable and consistent basis of allocation can be identified, corporate assets are also allocated to individual CGUs, or otherwise they are allocated to the smallest group of CGUs for which a reasonable and consistent allocation basis can be identified.

A CGU is the smallest identifiable group of assets that generates cash flow that is largely independent of cash flows from other assets or group of assets. The Company's CGU (drug development) is defined as a research programme that has the potential to be commercialized at some point in the future. Achievement of certain milestones within the current central nervous system research programme will determine when a new CGU comes into existence.

Intangible assets with indefinite useful lives are tested for impairment at least annually, and whenever there is an indication that the asset may be impaired.

Recoverable amount is the higher of fair value less costs to sell and value in use. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset for which the estimates of future cash flows have not been adjusted.

If the recoverable amount of an asset (or CGU) is estimated to be less than its carrying amount, the carrying amount of the asset (or CGU) is reduced to its recoverable amount. An impairment loss is recognised immediately in profit or loss, unless the relevant asset is carried at a revalued amount, in which case the impairment loss is treated as a revaluation decrease.

Where an impairment loss subsequently reverses, the carrying amount of the asset (or CGU) is increased to the revised estimate of its recoverable amount, but so that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognised for the asset (or CGU) in prior years. A reversal of an impairment loss is recognised immediately in profit or loss, unless the

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relevant asset is carried at a revalued amount, in which case the reversal of the impairment loss is treated as a revaluation increase.

(m) **Income Tax**

Income tax expense represents the sum of the tax currently payable and deferred tax.

Current Tax

The tax currently payable is based on taxable profit for the year. Taxable profit differs from profit before tax as reported in the consolidated statement of profit or loss and other comprehensive income because of items of income or expense that are taxable or deductible in other years and items that are never taxable or deductible. The Group's current tax is calculated using tax rates that have been enacted or substantively enacted by the end of the reporting period.

Deferred Tax

Deferred tax is recognised on temporary differences between the carrying amounts of assets and liabilities in the consolidated financial statements and the corresponding tax bases used in the computation of taxable profit. Deferred tax liabilities are generally recognised for all taxable temporary differences. Deferred tax assets are generally recognised for all deductible temporary differences to the extent that it is probable that taxable profits will be available against which those deductible temporary differences can be utilized. Such deferred tax assets and liabilities are not recognised if the temporary difference arises from the initial recognition (other than in a business combination) of assets and liabilities in a transaction that affects neither the taxable profit nor the accounting profit. In addition, deferred tax liabilities are not recognised if the temporary difference arises from the initial recognition of goodwill.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the period in which the liability is settled or the asset realised, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of the reporting period. The measurement of deferred tax liabilities and assets reflects the tax consequences that would follow from the manner in which the Group expects, at the end of the reporting period, to recover or settle the carrying amount of its assets and liabilities.

Deferred tax liabilities and assets are offset when there is a legally enforceable right to set off current tax assets against current tax liabilities and when they relate to income taxes levied by the same taxation authority and the Group intends to settle its current tax assets and liabilities on a net basis.

Current and Deferred Tax for the Year

Current and deferred tax are recognised in profit or loss, except when they relate to items that are recognised in other comprehensive income or directly in equity, in which case the current and deferred tax are also recognised in other comprehensive income or directly in equity, respectively. Where current tax or deferred tax arises from the initial accounting for a business combination, the tax effect is included in the accounting for the business combination.

Tax Consolidation Legislation

Bionomics and its wholly owned Australian controlled entities have implemented the tax consolidation legislation effective 31 December 2005.

The head entity, Bionomics Limited, and the controlled entities in the tax consolidated group account for their own current and deferred tax amounts. These tax amounts are measured as if each entity in the tax consolidated group continues to be a stand-alone taxpayer in its own right.

In addition to its own current and deferred tax amounts, Bionomics Limited also recognizes the current tax liabilities (or assets) and the deferred tax assets arising from unused tax losses and unused tax credits assumed from controlled entities in the tax consolidated group.

Assets or liabilities arising under tax funding agreements with the tax consolidated entities are recognised as amounts receivable from or payable to other entities in the Group.

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Any difference between the amounts assumed and amounts receivable or payable under the tax funding agreement are recognised as a contribution to (or distribution from) wholly-owned tax consolidated entities.

(n) Intangible Assets

(i) Intellectual Property

Acquired intellectual property is recognised as an asset at cost and amortised over its useful life. There is currently no internally generated intellectual property that has been capitalised. Intellectual property with a finite life is amortised on a straight-line basis over that life. Intellectual property with an indefinite useful life is subjected to an annual impairment review. There is currently no intellectual property with an indefinite life.

Current useful life of all existing intellectual property is in the range of 15 to 20 years.

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at each balance date.

(ii) Goodwill

Goodwill arising on an acquisition of a business is carried at cost as established at the date of the acquisition of the business (see Note 2(d) above) less accumulated impairment losses, if any.

For the purposes of impairment testing, goodwill is allocated to the Group's CGU that is expected to benefit from the synergies of the combination.

A CGU to which goodwill has been allocated is tested for impairment annually, or more frequently when there is an indication that the CGU may be impaired. If the recoverable amount of the CGU is less than its carrying amount, the impairment loss is allocated first to reduce the carrying amount of any goodwill allocated to the CGU and then to the other assets of the CGU pro rata based on the carrying amount of each asset in the CGU. Any impairment loss for goodwill is recognised directly in profit or loss. An impairment loss recognised for goodwill is not reversed in subsequent periods.

On disposal of the relevant CGU, the attributable amount of goodwill is included in the determination of the profit or loss on disposal.

(iii) Intangible Assets Acquired in a Business Combination

Intangible assets acquired in a business combination and recognised separately from goodwill are initially recognised at their fair value at the acquisition date (which is regarded as their cost).

Subsequent to initial recognition, intangible assets acquired in a business combination are reported at cost less accumulated amortisation and accumulated impairment losses, on the same basis as intangible assets that are acquired separately.

(o) Issued Capital

Ordinary shares are classified as equity.

Incremental costs directly attributable to the issue of new shares or options, or for the acquisition of a business, are deducted directly from equity.

(p) Leases

The Group assesses whether a contract is or contains a lease, at inception of the contract. That is, if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

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The Group as Lessee

The Group assesses whether a contract is or contains a lease, at inception of the contract. The Group recognizes a right-of-use asset and a corresponding lease liability with respect to all lease arrangements in which it is the lessee, except for short-term leases (defined as leases with a lease term of 12 months or less) and leases of low value assets (such as tablets and personal computers, small items of office furniture and telephones).

For these leases, the Group recognizes the lease payments as an operating expense on a straight-line basis over the term of the lease unless another systematic basis is more representative of the time pattern in which economic benefits from the leased assets are consumed.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted by using the rate implicit in the lease. If this rate cannot be readily determined, the lessee entity uses its incremental borrowing rate.

Lease payments included in the measurement of the lease liability comprise:

- Fixed lease payments (including in-substance fixed payments), less any lease incentives receivable;
- Variable lease payments that depend on an index or rate, initially measured using the index or rate at the commencement date;
- The amount expected to be payable by the lessee under residual value guarantees;
- The exercise price of purchase options, if the lessee is reasonably certain to exercise the options, and
- Payments of penalties for terminating the lease if the lease term reflects the exercise of an option to terminate the lease.

The lease liability is presented as a separate line in the consolidated statement of financial position.

The lease liability is subsequently measured by increasing the carrying amount to reflect interest on the lease liability (using the effective interest method) and by reducing the carrying amount to reflect the lease payments made.

The Group remeasures the lease liability (and makes a corresponding adjustment to the related right-of-use asset) whenever:

- The lease term has changed or there is a significant event or change in circumstances resulting in a change in the assessment of exercise of a purchase option, in which case the lease liability is remeasured by discounting the revised lease payments using a revised discount rate.
- The lease payments change due to changes in an index or rate or a change in expected payment under a guaranteed residual value, in which cases the lease liability is remeasured by discounting the revised lease payments using an unchanged discount rate (unless the lease payments change is due to a change in a floating interest rate, in which case a revised discount rate is used).
- A lease contract is modified, and the lease modification is not accounted for as a separate lease, in which case the lease liability is remeasured based on the lease term of the modified lease by discounting the revised lease payments using a revised discount rate at the effective date of the modification.

The Group did not make any such adjustments during the periods presented.

The right-of-use assets comprise the initial measurement of the corresponding lease liability, lease payments made at or before the commencement day, less any lease incentives received and any initial direct costs. They are subsequently measured at cost less accumulated depreciation and impairment losses.

Right-of-use assets are depreciated over the shorter period of lease term and useful life of the underlying asset. Current useful life of right-to-use assets is 5 years.

If a lease transfers ownership of the underlying asset or the cost of the right-of-use asset reflects that the Group expects to exercise a purchase option, the related right-of-use asset is depreciated over the useful life of the underlying asset. The depreciation starts at the commencement date of the lease.

The right-of-use assets are presented as a separate line in the consolidated statement of financial position.

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The Group applies IAS 36 to determine whether a right-of-use asset is impaired and accounts for any identified impairment loss as described in Note 2(l) above.

Group as Lessor

Leases in which the Group does not transfer substantially all the risks and rewards incidental to ownership of an asset are classified as operating leases. Rental income arising is accounted for on a straight-line basis over the lease term and is included in revenue in the statement of profit or loss due to its operating nature. Initial direct costs incurred in negotiating and arranging an operating lease are added to the carrying amount of the leased asset and recognised over the lease term on the same basis as rental income. Contingent rents are recognised as revenue in the period in which they are earned.

(q) Property, Plant and Equipment

Plant and equipment are stated at cost less accumulated depreciation or accumulated impairment losses, where applicable.

Depreciation is recognised so as to write off the cost of assets less their residual values over their useful lives, using the diminishing value or straight-line methods, depending on the type of asset. The estimated useful lives, residual values and depreciation method are reviewed at the end of each reporting period.

The depreciation rates for plant and equipment are 20 – 40%.

An item of property, plant and equipment is derecognized upon disposal or when no future economic benefits are expected to arise from the continued use of the asset. Any gain or loss arising on the disposal or retirement of an item of property, plant and equipment is determined as the difference between the sales proceeds and the carrying amount of the asset and is recognised in profit or loss.

(r) Research and Development

Expenditure on research activities, undertaken with the prospect of obtaining new scientific or technical knowledge and understanding, is recognised as an expense when it is incurred. Expenditures on development activities are capitalised only when technical feasibility studies identify that the project will deliver future economic benefits and these benefits can be measured reliably. Development costs have a finite life and are amortised on a systematic basis matched to the future economic benefits over the useful life of the project. At year end there are currently no capitalised development costs.

(s) Revenue Recognition

- (i) License revenues in connection with licensing of the Group's intellectual property (including patents) to collaborators are recognised as a right to use the entity's intellectual property as it exists at the point in time at which the license is granted. This is because the contracts for the license of intellectual property are distinct and do not require, nor does the customer reasonably expect, that the Group will undertake further activities that significantly affect the intellectual property to which the collaborator has rights.
- (ii) Although the Group is entitled to sales-based royalties from any eventual sales of goods and services to third parties using the intellectual property transferred, these royalty arrangements do not of themselves indicate that the collaborator would reasonably expect the Group to undertake such activities, and no such activities are undertaken or contracted in practice. Accordingly, the promise to provide rights to the Group's intellectual property is accounted for as a performance obligation satisfied at a point in time.

The following consideration is received in exchange for licenses of intellectual property:

- (a) Up-front payments - These are fixed amounts and are recognised at the point in time when the Group transfers the intellectual property to the collaborator.
- (b) Milestone payments - These are variable considerations that depends upon the collaborator reaching certain milestones in relation to the intellectual property licensed. Such amounts are only recognised when it is highly probable that a significant reversal in the amount of cumulative revenue recognised will not occur when the uncertainty associated with the variable

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- consideration (that is, the collaborator meeting the conditions to trigger payment) is subsequently resolved.
- (c) Sales-based royalties - These are variable consideration amounts promised in exchange for the license of intellectual property that occur late in the collaborator's development of the intellectual property and are recognised when the sales to third parties occur (as the performance obligation to transfer the intellectual property to the collaborator is already satisfied).
- (iii) The Group, until March 3, 2020 when its French subsidiaries were sold, performed contracted research and development. For the year ended June 30, 2020 this revenue was disclosed under discontinued operations (see Note 36 for additional information). For this contracted research and development work, the customer controlled all the work in progress as the work was being carried out, as the work is called out to the customer's specification and if a contract was terminated by the customer, then the Group was entitled to reimbursement of the costs incurred to date, including a reasonable margin. Invoices were issued according to contractual terms and invoiced amounts are presented as other receivables.
- Any amounts received from customers prior to the performance obligations being completed were recorded as unearned income and held on the balance sheet, until the relevant performance obligations had been completed in line with the policies above.
- The Group had no contracts where the period between the transfer of the promised goods or services to the customer and payment by the customer exceeds one year. As a consequence, the Group did not adjust any of the transaction prices for the time value of money
- (iv) Rental income is recognised on a straight-line basis over the term of the lease (refer to note 2(p) "Group as lessor" for further comments).

NOTE 3: CRITICAL ACCOUNTING ESTIMATES AND JUDGEMENTS

The preparation of the consolidated financial statements requires the Group to make estimates and judgements 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 the financial statements. The Group analyses the estimates and judgements and base estimates and judgements on historical experience and various other assumptions that are believed to be reasonable under the circumstances. Actual results may vary from the estimates. The significant accounting policies are detailed in Note 2. Summarised below are the accounting policies of particular importance to the portrayal of the financial position and results of operations and that require the application of significant judgement or estimates by management.

Impairment of Goodwill and Other Intangible Assets

The Group assesses 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 higher of value in use and fair value less cost of disposal of the CGU to which goodwill or other intangible assets have been allocated. The value in use calculation is judgmental in nature and requires the Group to make a number of estimates including the future cash flows expected to arise from the CGU based on actual current market deals for drug compounds within the CGU 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 comparables probability of realising projected milestone and royalty payments. When the carrying value of the CGU exceeds its recoverable amount, the CGU is considered impaired and the assets in the CGU are written down to their recoverable amount. Impairment losses are recognised in the consolidated statement of profit or loss and other comprehensive income. A detailed valuation was performed as of June 30, 2022 and each computed recoverable amount (based on a value-in-use model) of the CGU was in excess of the carrying amount, respectively. As a result of this evaluation, it was determined that no impairment of goodwill or other intangible assets existed at June 30, 2022.

Contingent Consideration

As a result of the acquisition of Eclipse Therapeutic, Inc ("Eclipse") during the year ended June 30, 2013, the Group determines and recognizes at each reporting date the fair value of the additional consideration that may be payable to Eclipse security holders due to potential royalty payments based on achieving late-stage development success or

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partnering outcomes based on Eclipse assets. Such potential earn-out payments are recorded at fair value and include a number of significant estimates including adjusted revenue projections and expenses, probability of such projections and a suitable discount rate to calculate fair value (see Note 30 for further information).

NOTE 4: SEGMENT INFORMATION

The Group operates in one segment (CGU) being “drug development” in Australia. This is the basis on which its internal reports are reviewed and used by the Board of Directors (the “chief operating decision maker”) in monitoring, assessing performance and in determining the allocation of resources.

The results, assets and liabilities from this segment are equivalent to the consolidated financial statements.

NOTE 5: REVENUE, OTHER INCOME AND OTHER GAINS AND LOSSES

	2022 A\$	2021 A\$	2020 A\$
Revenue from Continuing Operations			
Licenses	263,634	-	46,662
	<u>263,634</u>	<u>-</u>	<u>46,662</u>
Other Income from Continuing Operations			
Interest income	9,869	5,756	58,369
Rent	6,674	203,014	200,284
Government Research and Development Incentives (i)	5,791,688	928,073	2,945,600
Government assistance COVID-19 (Cash flow boost)	-	50,000	50,000
Government assistance COVID-19 (Jobkeeper)	-	121,500	58,500
	<u>5,808,231</u>	<u>1,308,343</u>	<u>3,312,753</u>

- (i) The Government Research and Development Incentives include cash refunds provided by the Australian Government for 43.5% (2021: 43.5%, 2020: 43.5%) of eligible research and development expenditures by Australian entities having a tax loss and less than A\$20 million in revenue. The grants are calculated at the end of the fiscal year to which they relate, based on the expenses incurred in and included in the fiscal year's Australian income tax return after registration of the research and development activities with the relevant authorities. There are no unfulfilled conditions or other contingencies attaching to the Government Research and Development Incentive.

	2022 A\$	2021 A\$	2020 A\$
Other gains and losses from Continuing Operations			
Net (loss)/gain arising on changes in fair value of contingent consideration (Note 30)	(936,354)	3,212,503	4,823,874
Net gain arising on modification of borrowings measured at amortised costs that were not derecognized (Note 18)	-	-	199,089
Net realised and unrealised foreign currency gains	356,166	1,081,438	(621,016)
(Loss) on disposal of plant and equipment	(1,827)	(21,010)	173,934
	<u>(582,015)</u>	<u>4,272,931</u>	<u>4,575,881</u>

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NOTE 6: EXPENSES RELATING TO CONTINUING OPERATIONS

	2022 A\$	2021 A\$	2020 A\$
Loss before income tax benefit includes the following specific expenses:			
Finance expenses			
- Interest expense on bank and other loans	-	618,586	1,170,027
- Interest expense on lease liabilities	26,872	26,934	79,938
- Amortisation of transaction costs (Note18)	-	252,019	29,649
- Accrual of final payment (Note 18)	-	528,819	544,357
- Bank fees	17,293	17,527	22,496
	<u>44,165</u>	<u>1,443,885</u>	<u>1,846,467</u>
Employment benefit expenses of:			
- Wages and salaries	2,901,689	2,577,954	3,097,949
- Superannuation	266,127	148,662	213,769
- Share-based payments	2,829,689	1,308,349	55,355
	<u>5,997,505</u>	<u>4,034,965</u>	<u>3,367,073</u>
Amortisation of non-current assets			
- Plant and equipment (Note 13)	2,681	45,553	91,860
- Right-of-use assets (rental property) (Note 14)	193,358	762,813	748,571
- Intellectual property (Note 16)	913,373	892,512	1,328,244
	<u>1,109,412</u>	<u>1,700,878</u>	<u>2,168,675</u>
Rental expense on operating leases (low value assets)			
- Minimum lease payments	5,260	7,277	7,506

NOTE 7: INCOME TAXES RELATING TO CONTINUING OPERATIONS

	2022 A\$	2021 A\$	2020 A\$
(a) Income Tax Recognised in Profit or Loss			
<u>Current tax</u>			
In respect of the current year	-	-	-
In respect of the prior year	-	-	-
	<u>-</u>	<u>-</u>	<u>-</u>
<u>Deferred tax</u>			
Recognised in current year	(191,808)	(187,427)	(207,612)
	<u>(191,808)</u>	<u>(187,427)</u>	<u>(207,612)</u>
Total income tax benefit	<u>(191,808)</u>	<u>(187,427)</u>	<u>(207,612)</u>

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	2022 A\$	2021 A\$	2020 A\$
(b) Reconciliation to Accounting Loss			
Loss from continuing operations	(21,951,166)	(8,884,464)	(6,026,587)
Tax at the Australian tax rate of 25% (2021 & 2020: 30%)	(5,487,792)	(2,665,339)	(1,807,976)
<i>Tax effect of non-deductible / non-assessable amounts</i>			
Exempt income from government assistance	(1,447,922)	(293,422)	(898,680)
Entertainment expenses	1,231	727	1,355
Net gain arising on changes in fair value of contingent consideration	234,089	(963,751)	(1,447,162)
Share-based payments	707,422	392,505	16,607
Research and development expenditure	3,328,556	640,050	2,013,477
Amortisation of share issue costs	(285,631)	-	-
Temporary differences not recorded as an asset	(58,374)	(632,779)	(68,181)
Tax losses not recorded	2,779,547	3,253,265	1,981,695
Effect of different tax rates in other jurisdictions	37,066	81,317	1,253
	<u>(191,808)</u>	<u>(187,427)</u>	<u>(207,612)</u>

	2022 A\$	2021 A\$
(c) Net Deferred Tax Liability Recognised		
Net deferred tax liability is attributable to the following deferred tax asset/(liability) items:		
Intangibles denominated in USD	(2,066,037)	(2,088,608)
Tax losses denominated in USD	267,412	246,305
	<u>(1,798,625)</u>	<u>(1,842,303)</u>
Movement in Net Deferred Tax Liability		
Opening balance	(1,842,303)	(2,203,340)
Recognized in income		
- Continuing operations	191,808	187,427
- Discontinuing operations	-	-
Recognized in equity	(148,130)	173,610
Derecognized on disposal of subsidiaries (Note 35)	-	-
Closing balance	<u>(1,798,625)</u>	<u>(1,842,303)</u>

(d) Net Deferred Tax Asset Not Recognised		
Revenue tax losses	25,439,594	27,181,188
Net temporary difference	3,460,261	2,851,336
	<u>28,899,855</u>	<u>30,032,524</u>

Deferred tax assets have not been recognized in respect to these items as it is not probable at this time that future taxable profits will be available against which the Group can utilize the benefit.

(f) Tax Consolidation

Relevance of Tax Consolidation to the Group

The Company and all its wholly-owned Australian resident entities are part of a tax-consolidated group under Australian taxation law. Bionomics is the head entity in the tax-consolidated group. Tax expense/benefit, deferred tax liabilities and deferred tax assets arising from temporary differences of the members of the tax-consolidated group are recognised in the separate financial statements of the members of the tax-consolidated group using the 'separate taxpayer within group' approach by reference to the carrying amounts in the separate financial statements of each entity and the tax values applying under tax consolidation. Current tax liabilities and assets and deferred tax assets arising from unused tax losses and relevant tax credits of the members of the tax-consolidated group are recognised by the Company (as head entity in the tax-consolidated group).

Notes to the Financial Statements
for the financial year ended June 30, 2022, 2021 and 2020

NOTE 8: CASH AND CASH EQUIVALENTS

Cash at the end of the financial year as shown in the statements of cash flows is reconciled to items in the Consolidated Statement of Financial Position as follows:

	2022 A\$	2021 A\$
Current		
Cash at bank and on hand	33,564,857	28,499,449
	<u>33,564,857</u>	<u>28,499,449</u>

The weighted average interest rate on these deposits is 1.15% per annum (2021: 0.1% per annum).

NOTE 9: OTHER FINANCIAL ASSETS

	2022 A\$	2021 A\$
Restricted deposits held as security and not available for use	<u>119,000</u>	<u>554,640</u>
Disclosed in the financial statement as:		
Current assets	-	435,640
Non-current assets	119,000	119,000
	<u>119,000</u>	<u>554,640</u>

The Group holds restricted term deposits of A\$119,000 (2021: A\$383,883, \$51,757 and A\$119,000), with a maturity date of June 3, 2023 (2021: September 11, 2021, September 23, 2021 and June 3, 2022 respectively) as security for a bank guarantee (Note 31 (ii)) that is not available for use. The term deposits will be extended on maturity until the bank guarantee ceases to be required. The effective interest rate on these deposits is 1.95% (2021:0.71%).

NOTE 10: TRADE AND OTHER RECEIVABLES

	2022 A\$	2021 A\$
Current		
Other receivables	42,483	192,885
Loss allowance	-	-
	<u>42,483</u>	<u>192,885</u>
GST receivables	21,877	7,327
	<u>64,360</u>	<u>200,212</u>

NOTE 11: OTHER ASSETS

	2022 A\$	2021 A\$
Current		
Prepayments	1,461,078	860,793
Accrued income	190	2,837
	<u>1,461,268</u>	<u>863,630</u>

Notes to the Financial Statements
for the financial year ended June 30, 2022, 2021 and 2020

NOTE 12: SUBSIDIARIES

Details of the Group's subsidiaries at the end of the reporting period are as follows:

Entity	Principal activity	Country of incorporation	Percentage owned	
			2022 %	2021 %
Head Entity				
Bionomics Limited	Research and Development	Australia		
Subsidiaries of Bionomics Limited				
Iliad Chemicals Pty Ltd	Asset owner	Australia	100	100
Bionomics Inc	Asset owner	United States	100	100

NOTE 13: PROPERTY, PLANT AND EQUIPMENT

	Plant and Equipment at cost A\$	Total A\$
Cost at July 1, 2020	1,373,704	1,373,704
Additions	1,468	1,468
Disposals	(1,268,419)	(1,268,419)
Cost at June 30, 2021	106,753	106,753
Additions	1,544	1,544
Disposals	(36,262)	(36,262)
Cost at June 30, 2022	72,035	72,035
Accumulated depreciation at July 1, 2020	(1,089,748)	(1,089,748)
Depreciation ^(a)	(45,553)	(45,553)
Disposals	1,036,775	1,036,775
Accumulated depreciation at June 30, 2021	(98,526)	(98,526)
Depreciation ^(a)	(2,681)	(2,681)
Disposals	34,344	34,344
Accumulated depreciation at June 30, 2022	(66,863)	(66,863)
Net Carrying Amounts at June 30, 2021	8,227	8,227
Net Carrying Amounts at June 30, 2022	5,172	5,172

a) Depreciation is disclosed in the Consolidated Statement of Profit or Loss and Other Comprehensive Income as follows

	2022 A\$	2021 A\$	2020 A\$
Continuing operations	2,681	45,553	91,860
Discontinued operations	-	-	113,009
	<u>2,681</u>	<u>45,553</u>	<u>204,869</u>

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for the financial year ended June 30, 2022, 2021 and 2020

NOTE 14: RIGHT-OF-USE ASSETS

	2022 A\$	2021 A\$
Cost	854,500	2,374,100
Accumulated depreciation	(185,142)	(1,511,384)
	<u>669,358</u>	<u>862,716</u>
Opening balance July 1	862,716	771,029
Addition of new property being rented	-	854,500
Depreciation ^(a)	(193,358)	(762,813)
Closing balance June 30	<u>669,358</u>	<u>862,716</u>

a) Depreciation is disclosed in the Consolidated Statement of Profit or Loss and Other Comprehensive Income as follows

	2022 A\$	2021 A\$	2020 A\$
Continuing operations	193,358	762,813	748,571
Discontinued operations	-	-	116,075
	<u>193,358</u>	<u>762,813</u>	<u>864,646</u>

Refer to Note 19 for information on non-current assets pledged as security for lease liabilities by the Group.

NOTE 15: GOODWILL

Carrying amount at July 1, 2020	12,872,387
Additions	-
Foreign currency exchange differences	(471,644)
Carrying amount at June 30, 2021	<u>12,400,743</u>
Additions	-
Foreign currency exchange differences	467,379
Carrying amount at June 30, 2022	<u>12,868,122</u>

Impairment Tests

As identified in Note 4 the Group has only one CGU, drug development. Management tests annually whether goodwill has suffered any impairment, in accordance with the accounting policy stated in Note 2(n)(i) and (ii), and Note 2(l), respectively. For the purpose of impairment testing all goodwill is allocated to the drug development CGU.

The recoverable amount of the drug development CGU is determined based on a value in use calculation which uses cash flow projections based on observable market comparables for drug compounds within the CGU over a period of twenty years covering drug discovery, development, approval and marketing, and a post-tax discount rate of 17% (2021: 15%). The Group is currently in its research phase and a 5 year forecast would not provide reasonable consideration of the timeframe, revenue and costs projections. The cash flow projections are weighted based on the observable market comparables probability of realising projected milestone and royalty payments.

Management believes that the application of discounted cash flows of observable market comparables for one drug compound is reasonable to be applied to other compounds within the CGU at their respective development phases.

Management believes that any reasonably possible change in the key assumptions on which recoverable amount is based would not cause the aggregate carrying amount to exceed the aggregate recoverable amount of the CGU.

Notes to the Financial Statements
for the financial year ended June 30, 2022, 2021 and 2020

No growth rates or terminal values have been included in the forecast, as the full development lifecycle has been taken into account with the cashflows.

NOTE 16: OTHER INTANGIBLE ASSETS

Intellectual Property

The acquired intellectual property relates to KV1.3 compound, VDA compound, MultiCore technology and cancer stem cell technology, and is carried at its cost as at its date of acquisition, less accumulated amortisation and impairment charges. There is currently no internally generated intellectual property capitalised.

	KV1.3 compound A\$	VDA compound A\$	MultiCore technology A\$	Cancer stem cell technology A\$	Total A\$
Gross carrying amount at July 1, 2020	1,546,542	2,282,527	1,265,590	19,210,485	24,305,144
Additions	-	-	-	-	-
Foreign currency exchange differences	-	-	-	(1,529,124)	(1,529,124)
Gross carrying amount at June 30, 2021	<u>1,546,542</u>	<u>2,282,527</u>	<u>1,265,590</u>	<u>17,681,361</u>	<u>22,776,020</u>
Additions	-	-	-	-	-
Foreign currency exchange differences	-	-	-	1,515,296	1,515,296
Gross carrying amount at June 30, 2022	<u><u>1,546,542</u></u>	<u><u>2,282,527</u></u>	<u><u>1,265,590</u></u>	<u><u>19,196,657</u></u>	<u><u>24,291,316</u></u>
Accumulated amortisation amount at July 1, 2020	(1,546,542)	(2,282,527)	(1,265,590)	(7,444,073)	(12,538,732)
Amortisation ^(a)	-	-	-	(892,512)	(892,512)
Foreign currency exchange differences	-	-	-	600,979	600,979
Accumulated amortisation amount at June 30, 2021	<u>(1,546,542)</u>	<u>(2,282,527)</u>	<u>(1,265,590)</u>	<u>(7,735,606)</u>	<u>(12,830,265)</u>
Amortisation ^(a)	-	-	-	(913,373)	(913,373)
Foreign currency exchange differences	-	-	-	(709,404)	(709,404)
Accumulated amortisation amount at June 30, 2022	<u><u>(1,546,542)</u></u>	<u><u>(2,282,527)</u></u>	<u><u>(1,265,590)</u></u>	<u><u>(9,358,383)</u></u>	<u><u>(14,453,042)</u></u>
Net carrying amount June 30, 2021	<u><u>-</u></u>	<u><u>-</u></u>	<u><u>-</u></u>	<u><u>9,945,755</u></u>	<u><u>9,945,755</u></u>
Net carrying amount June 30, 2022	<u><u>-</u></u>	<u><u>-</u></u>	<u><u>-</u></u>	<u><u>9,838,274</u></u>	<u><u>9,838,274</u></u>

a) Depreciation is disclosed in the Consolidated Statement of Profit or Loss and Other Comprehensive Income as follows:

	2022 A\$	2021 A\$	2020 A\$
Continuing operations	913,373	892,512	1,328,244
Discontinued operations	-	-	45,627
	<u>913,373</u>	<u>892,512</u>	<u>1,373,871</u>

NOTE 17: TRADE AND OTHER PAYABLES

	2022 A\$	2021 A\$
Current		
Trade payables	1,556,881	1,028,744
Accrued expenses	1,229,399	785,646
	<u><u>2,786,280</u></u>	<u><u>1,814,390</u></u>

The average credit period on purchases of goods is 45 days. No interest is paid on the trade payables. The Group has financial risk management policies in place to ensure that all payables are paid within the credit timeframe.

Notes to the Financial Statements
for the financial year ended June 30, 2022, 2021 and 2020

NOTE 18: BORROWINGS

	2022 A\$	2021 A\$
Current liabilities	-	-
Non-current liabilities	-	-
	<u>-</u>	<u>-</u>

During April 2021 the equipment mortgage loans and the bank loan (which was denominated in US dollars) were fully repaid.

	2022 A\$	2021 A\$
Loan Movement Schedule		
Opening Balance – July 1	-	11,444,129
Accrual of bank loan final payment ⁽ⁱ⁾	-	528,819
Repayments - principal	-	(9,170,741)
- final payment ⁽ⁱ⁾	-	(1,916,398)
Net gain arising on modification of bank loan (due to extension of loan) that was not derecognized ⁽ⁱⁱ⁾	-	-
Transaction costs associated with obtaining interest only period ⁽ⁱⁱⁱ⁾	-	-
Amortisation of costs ⁽ⁱⁱⁱ⁾	-	252,019
Foreign currency exchange differences	-	(1,137,828)
Closing Balance – June 30	<u>-</u>	<u>-</u>

- (i) In addition to the payment of principal and interest over the term of the bank loan, a final payment was required under the bank loan, calculated at a percentage of the original principal borrowed. This liability was being accrued (using the effective interest method) over the term of the loan and the amount accrued prior to the loan being fully repaid was US\$1,477,500 (July 1, 2020 was US\$1,079,030).
- (ii) As a result of the bank loan being extended to January 1, 2022 (that occurred during the year ended June 30, 2020) the accrual of the bank loan final payment was remeasured resulting in a reduction in the liability that had been accrued as the modification to the loan did not qualify for derecognition of the loan.
- (iii) The transaction costs related to costs incurred in obtaining the six-month interest only period and extension of the bank loan. These costs were being amortized over the remaining term of the bank loan.

NOTE 19: LEASE LIABILITIES

	2022 A\$	2021 A\$	2020 A\$
Secured – at amortised costs			
Loan Movement Schedule			
Opening Balance – July 1	867,841	793,148	-
Adoption of new leasing accounting standard	-	-	2,993,675
New lease for new property - being rented	-	854,500	-
Repayments	(174,218)	(779,807)	(826,942)
Derecognized on disposal of subsidiaries (Note 34)	-	-	(1,440,322)
Effect of foreign currency exchange differences	-	-	66,737
Closing Balance – June 30	<u>693,623</u>	<u>867,841</u>	<u>793,148</u>

Disclosed in the financial statements as:

Notes to the Financial Statements
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Current liabilities	160,040	174,218	767,711
Non-current liabilities	533,583	693,623	25,437
	<u>693,623</u>	<u>867,841</u>	<u>793,148</u>

Lease liabilities relate to building leases and is effectively secured by the buildings being leased (Note 14).

The total Group cash outflows for leases is set out below:

	2022 A\$	2021 A\$	2020 A\$
Principal element of lease payments	174,218	779,807	826,942
Interest element of lease payments - continuing operations	26,872	26,934	79,938
Interest element of lease payments - discontinuing operations	-	-	33,176
Total cash outflows for leases	<u>201,090</u>	<u>806,741</u>	<u>940,056</u>

The Group's lease contracts include extension and termination options. These options are negotiated by management to provide flexibility in managing the leased-asset portfolio and align with the

Group's business needs.

Set out below are the undiscounted potential future rental payments relating to periods following the exercise date of extension options that are not included in the lease term:

	Within five years A\$	More than five years A\$	Total A\$
As at June 30, 2022			
Extension options expected not to be exercised	-	1,183,105	1,183,105
As at June 30, 2021			
Extension options expected not to be exercised	-	1,183,105	1,183,105

NOTE 20: PROVISIONS

	2022 A\$	2021 A\$
Current		
Employee benefits	409,320	371,936
Non-Current		
Employee benefits	10,460	6,782

Notes to the Financial Statements
for the financial year ended June 30, 2022, 2021 and 2020

NOTE 21: ISSUED CAPITAL

(a) Issued capital

Movements in Ordinary Shares of the Company during the current period were as follows:

Date	Details	Number of shares	A\$
Ordinary Shares			
July 1, 2019	Opening balance	544,647,747	144,944,233
	Share issue - share placement	81,500,000	3,260,000
	Transfer from treasury stock	38,125	-
	Share issue costs	-	(48,228)
June 30, 2020	Closing balance	626,185,872	148,156,005
	Share issue - share placements (i)	185,757,511	21,229,874
	Share issue – rights (ii)	195,229,129	22,606,257
	Shares issued to employees	424,232	60,750
	Share issue costs	-	(423,492)
	Warrants issued -underwriting fee (iii)	-	(1,439,247)
June 30, 2021	Closing balance	1,007,596,744	190,190,147
	Shares issued on exercise of options (iv)	2,000,000	27,200
	Shares issued on exercise of warrants (iv)	8,000,000	480,000
	Transfer from share-based payments reserve as result of options and warrants being exercised	-	327,760
	Share issue in a US IPO and NASDAQ listing (v)	335,754,000	32,383,263
	Share issue costs	-	(5,712,611)
June 30, 2022	Closing balance	1,353,350,744	217,695,759
Treasury Stock			
July 1, 2019	Closing balance	38,125	-
	Share issue – Employee Share Plan Loan Agreements	(38,125)	-
June 30, 2020	Closing balance	-	-
	Share issue – Employee Share Plan Loan Agreements	-	-
June 30, 2021	Closing balance	-	-
	Share issue – Employee Share Plan Loan Agreements	-	-
June 30, 2022	Closing balance	-	-
Total Issued Capital		1,353,350,744	217,695,759

- (i) During the year ended June 30, 2021, the following share placements occurred:
- Issue of 54,333,000 shares at A\$0.04 per share raising A\$2,173,320. The share issue was approved by shareholders at a General Meeting held on August 26, 2020; and
 - Issue of 131,424,511 shares at A\$0.145 per share raising A\$19,056,554
- (ii) During the year ended June 30, 2021, the following rights issues occurred:
- Issue of 54,304,446 at A\$0.04 per share raising A\$2,172,178; and
 - Issue of 140,924,683 shares at A\$0.145 raising A\$20,434,079
- (iii) Shareholders at the General Meeting held on August 26, 2020 approved the issue of 150,000,000 warrants to Apeiron Investment Group Ltd (“Apeiron”) to subscribe for shares at A\$0.06 per share as consideration of underwriting a share issue that would raise at least A\$15,000,000. The warrants vested on 3 March 2021 when with the assistance of Apeiron a share placement was made that raised A\$15,991,634.
- (iv) During the year ended June 30, 2022, the following shares were issued:

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- Issue of 2,000,000 as a result of share options being exercised that had an exercise price of A\$0.0136 per option; and
 - Issue of 8,000,000 shares as a result of warrants being exercised that had an exercise price of A\$0.06 per warrant.
- (v) During the year ended June 30, 2022, 335,754,000 shares were issued in a US IPO and Nasdaq listing. The IPO and Nasdaq listing were approved by shareholders at the Annual General Meeting held on December 2, 2021.

Ordinary shares entitle the holder to participate in dividends and the proceeds on winding up of the Company in proportion to the number of and amounts paid on the shares held. On a show of hands every holder of ordinary shares present at a meeting in person or by proxy, is entitled to one vote and upon a poll each share is entitled to one vote.

(b) Share Options

When exercised, each option is convertible into one ordinary share.

The Bionomics Employee Equity Plan and Bionomics Employee Share Option Plan

The terms and conditions of the Bionomics Employee Equity Plan and Bionomics Employee Share Option Plan are summarised in Note 2(g)(iii).

Movement in unlisted share options:

	2022		2021		2020	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Opening balance at beginning of financial year	20,985,450	A\$0.12	6,364,550	A\$0.40	7,686,550	A\$0.41
Granted during the financial year	61,216,767	A\$0.18	15,500,000	A\$0.04	-	-
Forfeited during the financial year	-	-	(5,000)	A\$0.41	(582,500)	A\$0.44
Exercised during the financial year	(2,000,000)	A\$0.01	-	-	-	-
Expired during the financial year	(1,145,600)	A\$0.42	(874,100)	A\$0.45	(739,500)	A\$0.45
Closing balance at June 30	<u>79,056,617</u>	A\$0.16	<u>20,985,450</u>	A\$0.12	<u>6,364,550</u>	A\$0.40

The number of unlisted share options vested and exercisable at June 30, 2022 is 31,065,275 (2021: 20,056,450).

The weighted average remaining contractual life of any unlisted share options outstanding at the end of the year is 4.93 years (2021: 3.80 years).

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(i) Unlisted share options issued during the year ended June 30, 2022

On December 2, 2021, shareholders at the Annual General Meeting approved the issuing of 47,786,607 share options to subscribe for 47,786,607 shares at \$0.2014 per share to Dr Errol De Souza, Executive Chairman. The options were issued on December 22, 2021, details of the issue are set out below:

Grant date	Vesting date	Expiry date	Exercise price	Number	Fair value at date of issue
2-Dec-21	30-Sep-21	30-Sep-26	A\$0.2014	2,986,663	A\$0.0740
2-Dec-21	31-Dec-21	31-Dec-26	A\$0.2014	2,986,663	A\$0.0760
2-Dec-21	31-Mar-22	31-Mar-27	A\$0.2014	2,986,663	A\$0.0780
2-Dec-21	30-Jun-22	30-Jun-27	A\$0.2014	2,986,663	A\$0.0790
2-Dec-21	30-Sep-22	30-Sep-27	A\$0.2014	2,986,663	A\$0.0810
2-Dec-21	31-Dec-22	31-Dec-27	A\$0.2014	2,986,663	A\$0.0820
2-Dec-21	31-Mar-23	31-Mar-28	A\$0.2014	2,986,663	A\$0.0840
2-Dec-21	30-Jun-23	30-Jun-28	A\$0.2014	2,986,663	A\$0.0850
2-Dec-21	30-Sep-23	30-Sep-28	A\$0.2014	2,986,663	A\$0.0860
2-Dec-21	31-Dec-23	31-Dec-28	A\$0.2014	2,986,663	A\$0.0880
2-Dec-21	31-Mar-24	31-Mar-24	A\$0.2014	2,986,663	A\$0.0890
2-Dec-21	30-Jun-24	30-Jun-24	A\$0.2014	2,986,663	A\$0.0900
2-Dec-21	30-Sep-24	30-Jun-24	A\$0.2014	2,986,663	A\$0.0910
2-Dec-21	31-Dec-24	31-Dec-29	A\$0.2014	2,986,663	A\$0.0920
2-Dec-21	31-Mar-25	31-Mar-30	A\$0.2014	2,986,663	A\$0.0930
2-Dec-21	30-Jun-25	30-Jun-30	A\$0.2014	2,986,662	A\$0.0940
				47,786,607	

A Black-Scholes model was used to obtain the fair value of the above share options. Inputs used are summarised below:

Share price at date of issue	A\$0.125
Exercise price	A\$0.2014
Bionomics share volatility	85.53 %
Risk free interest rate	0.413 %

On December 2, 2021, shareholders at the Annual General Meeting approved the issuing of 13,430,160 share options to subscribe for 13,430,160 shares at A\$0.09645 per share to Dr Errol De Souza, Executive Chairman. The options were issued on 22 December 2021, details of the issue are set out below:

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Grant date	Vesting date	Expiry date	Exercise price	Number	Fair value at date of issue
2-Dec-21	31-Mar-22	31-Mar-27	A\$0.09645	839,385	A\$0.0900
2-Dec-21	30-Jun-22	30-Jun-27	A\$0.09645	839,385	A\$0.0910
2-Dec-21	30-Sep-22	30-Sep-27	A\$0.09645	839,385	A\$0.0920
2-Dec-21	31-Dec-22	31-Dec-27	A\$0.09645	839,385	A\$0.0940
2-Dec-21	31-Mar-23	31-Mar-28	A\$0.09645	839,385	A\$0.0950
2-Dec-21	30-Jun-23	30-Jun-28	A\$0.09645	839,385	A\$0.0960
2-Dec-21	30-Sep-23	30-Sep-28	A\$0.09645	839,385	A\$0.0970
2-Dec-21	31-Dec-23	31-Dec-28	A\$0.09645	839,385	A\$0.0980
2-Dec-21	31-Mar-24	31-Mar-29	A\$0.09645	839,385	A\$0.0980
2-Dec-21	30-Jun-24	30-Jun-29	A\$0.09645	839,385	A\$0.0990
2-Dec-21	30-Sep-24	30-Sep-29	A\$0.09645	839,385	A\$0.1000
2-Dec-21	31-Dec-24	31-Dec-29	A\$0.09645	839,385	A\$0.1010
2-Dec-21	31-Mar-25	31-Mar-30	A\$0.09645	839,385	A\$0.1020
2-Dec-21	30-Jun-25	30-Jun-30	A\$0.09645	839,385	A\$0.1020
2-Dec-21	30-Sep-25	30-Sep-30	A\$0.09645	839,385	A\$0.1030
2-Dec-21	31-Dec-25	31-Dec-30	A\$0.09645	839,385	A\$0.1040
				13,430,160	

A Black-Scholes model was used to obtain the fair value of the above share options. Inputs used are summarised below

Share price at date of issue	A\$0.125
Exercise price	A\$0.0965
Bionomics share volatility	85.53 %
Risk free interest rate	0.413 %

(ii) Unlisted share options issued during the year ended June 30, 2021

On August 28, 2020, the Company issued 15 million share options to subscribe for 15 million shares at A\$0.04 per share expiring on August 28, 2025 to key management personnel, details of the issue are set out below:

KMP	Number	Vesting conditions	Fair value at date of issue
Dr Errol De Souza	6,000,000	Company's share price reaching \$0.14 per share	A\$0.075
Dr Errol De Souza	6,000,000	Company's share price reaching \$0.24 per share	A\$0.071
Mr Jack Moschakis	1,000,000	Company's share price reaching \$0.14 per share	A\$0.133
Mr Jack Moschakis	1,000,000	Company's share price reaching \$0.24 per share	A\$0.118
Ms Liz Doolin	500,000	Company's share price reaching \$0.14 per share	A\$0.133
Ms Liz Doolin	500,000	Company's share price reaching \$0.24 per share	A\$0.118

The share options issued to Dr Errol De Souza were approved by shareholders at the general meeting held on August 26, 2020 and the share options issued to Mr Jack Moschakis and Ms Liz Doolin were approved by Directors on 28 August 2020.

A Monte Carlo model was used to obtain the fair value of the share options that were issued to Dr Errol De Souza and the share options issued to Mr Jack Moschakis and Ms Liz Doolin that vest when the Company's share price reach A\$0.24. A Black-Scholes model was used to obtain the fair value of the share options issued to Mr Jack Moschakis and Ms Liz Doolin that vest when the Company's share price reach \$0.14, as the share price had reached A\$0.14 when these shares options were approved to be issued. Inputs used are summarised below:

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	Dr Errol De Souza share options	Mr Jack Moschakis and Ms Liz Doolin share options
Share price at date of issue	A\$0.11	A\$0.15
Exercise price	A\$0.04	A\$0.04
Bionomics share volatility	105%	105%
Risk free interest rate	0.42%	0.43%

On November 20, 2020, the company issued 500,000 share options to subscribe for 500,000 shares at A\$0.1687 per share to Dr Jane Ryan (non-executive director). The issue of these options was approved by shareholders at the Annual General Meeting held on 20 November 2020, details of the share options issue are set out below:

Grant date	Vesting date	Expiry date	Exercise price	Number	Fair value at date of issue
20-Nov-20	20-Oct-21	20-Oct-26as at 06/30/20	A\$0.1687	100,000	A\$0.089
20-Nov-20	20-Oct-22	20-Oct-27	A\$0.1687	100,000	A\$0.095
20-Nov-20	20-Oct-23	20-Oct-28	A\$0.1687	100,000	A\$0.099
20-Nov-20	20-Oct-24	20-Oct-29	A\$0.1687	100,000	A\$0.103
20-Nov-20	20-Oct-25	20 Oct-30	A\$0.1687	100,000	A\$0.107

A Black-Scholes model was used to obtain the fair value of the above share options. Inputs used are summarised below:

Share price at date of issue	A\$0.13
Exercise price	A\$0.1687
Bionomics share volatility	89%
Risk free interest rate	0.30%

As a result of the rights issues that occurred during the year ended June 30, 2021, the exercise price of the above options was recalculated in accordance with the rules of the option plans, and the ASX listing rule 6.22.2.

Unlisted share options exercised during the year ended June 30, 2022

On September 2, 2021, 2,000,000 unlisted share options were exercised at A\$0.0136 per share. The share price at date of exercise was A\$0.19.

The table below lists share options outstanding at June 30, 2022:

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Grant date	Expiry date	Exercise price	Number of options	Fair value
20-Jul-15	20-Jul-22	A\$0.4077	15,000	A\$0.2371
5-Sep-17	5-Sep-22	A\$0.4136	368,050	A\$0.2839
9-Oct-15	9-Oct-22	A\$0.4311	5,000	A\$0.3216
10-Oct-13	10-Oct-22	A\$0.5750	15,000	A\$0.5233
28-Nov-16	28-Nov-22	A\$0.2349	200,000	A\$0.2505
28-Nov-16	28-Nov-22	A\$0.2866	100,000	A\$0.2377
28-Nov-16	28-Nov-22	A\$0.3556	5,000	A\$0.2227
11-Dec-12	11-Dec-22	A\$0.2912	100,000	A\$0.2155
17-Dec-13	11-Dec-22	A\$0.6960	100,000	A\$0.4318
17-Dec-13	17-Dec-22	A\$0.6611	4,000	A\$0.4385
18-Dec-12	18-Dec-22	A\$0.2912	5,000	A\$0.2535
24-Dec-15	24-Dec-22	A\$0.5125	100,000	A\$0.1658
30-Dec-15	30-Dec-22	A\$0.4838	50,000	A\$0.1772
27-Apr-15	27-Apr-23	A\$0.4765	4,000	A\$0.2466
1-May-13	1-May-23	A\$0.3481	64,000	A\$0.2697
6-May-16	6-May-23	A\$0.2936	50,000	A\$0.1961
25-May-15	25-May-23	A\$0.3982	260,600	A\$0.2654
20-Jul-15	20-Jul-23	A\$0.4077	15,000	A\$0.2513
5-Sep-17	5-Sep-23	A\$0.4136	10,000	A\$0.3062
9-Oct-15	9-Oct-23	A\$0.4311	5,000	A\$0.3376
10-Oct-13	10-Oct-23	A\$0.5750	5,000	A\$0.5415
10-Oct-13	10-Oct-23	A\$0.5750	10,000	A\$0.5415
4-Nov-16	4-Nov-23	A\$0.2327	4,000	A\$0.2448
28-Nov-16	28-Nov-23	A\$0.2349	200,000	A\$0.2621
28-Nov-16	28-Nov-23	A\$0.2866	200,000	A\$0.2504
28-Nov-16	28-Nov-23	A\$0.3556	5,000	A\$0.2370
17-Dec-13	17-Dec-23	A\$0.6611	4,000	A\$0.4573
24-Dec-15	24-Dec-23	A\$0.5125	100,000	A\$0.1798
30-Dec-15	30-Dec-23	A\$0.4838	50,000	A\$0.1912
2-Dec-21	31-Mar-24	A\$0.2014	2,986,663	A\$0.0890
27-Apr-15	27-Apr-24	A\$0.4765	4,000	A\$0.2601
6-May-16	6-May-24	A\$0.2936	50,000	A\$0.2068
25-May-15	25-May-24	A\$0.3982	260,600	A\$0.2780
2-Dec-21	30-Jun-24	A\$0.2014	2,986,663	A\$0.0900
2-Dec-21	30-Jun-24	A\$0.2014	2,986,663	A\$0.0910
20-Jul-15	20-Jul-24	A\$0.4077	15,000	A\$0.2640
5-Sep-17	5-Sep-24	A\$0.4136	10,000	A\$0.3236
9-Oct-15	9-Oct-24	A\$0.4311	5,000	A\$0.3521
4-Nov-16	4-Nov-24	A\$0.2327	4,000	A\$0.2546
28-Nov-16	28-Nov-24	A\$0.2349	200,000	A\$0.2721

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Grant date	Expiry date	Exercise price	Number of options	Fair value
28-Nov-16	28-Nov-24	A\$0.2866	200,000	A\$0.2616
28-Nov-16	28-Nov-24	A\$0.3556	5,000	A\$0.2495
24-Dec-15	24-Dec-24	A\$0.5125	100,000	A\$0.1925
30-Dec-15	30-Dec-24	A\$0.4838	50,000	A\$0.2038
27-Apr-15	27-Apr-25	A\$0.4765	4,000	A\$0.2722
6-May-16	6-May-25	A\$0.2936	50,000	A\$0.2164
25-May-15	25-May-25	A\$0.3982	260,600	A\$0.2893
20-Jul-15	20-Jul-25	A\$0.4077	15,000	A\$0.2756
28-Aug-20	28-Aug-25	A\$0.0136	6,000,000	A\$0.0750
28-Aug-20	28-Aug-25	A\$0.0136	6,000,000	A\$0.0710
28-Aug-20	28-Aug-25	A\$0.0136	500,000	A\$0.1330
28-Aug-20	28-Aug-25	A\$0.0136	500,000	A\$0.1180
5-Sep-17	5-Sep-25	A\$0.4136	10,000	A\$0.3388
9-Oct-15	9-Oct-25	A\$0.4311	5,000	A\$0.3653
4-Nov-16	4-Nov-25	A\$0.2327	4,000	A\$0.2633
28-Nov-16	28-Nov-25	A\$0.2349	200,000	A\$0.2810
28-Nov-16	28-Nov-25	A\$0.2866	200,000	A\$0.2716
28-Nov-16	28-Nov-25	A\$0.3556	5,000	A\$0.2605
24-Dec-15	24-Dec-25	A\$0.5125	100,000	A\$0.2039
30-Dec-15	30-Dec-25	A\$0.4838	50,000	A\$0.2152
6-May-16	6-May-26	A\$0.2936	50,000	A\$0.2251
5-Sep-17	5-Sep-26	A\$0.4136	10,000	A\$0.3520
2-Dec-21	30-Sep-26	A\$0.2014	2,986,663	A\$0.0740
20-Nov-20	20-Oct-26	A\$0.1519	100,000	A\$0.0890
4-Nov-16	4-Nov-26	A\$0.2327	4,000	A\$0.2710
28-Nov-16	28-Nov-26	A\$0.2349	200,000	A\$0.2890
28-Nov-16	28-Nov-26	A\$0.2866	200,000	A\$0.2804
28-Nov-16	28-Nov-26	A\$0.3556	5,000	A\$0.2703
2-Dec-21	31-Dec-26	A\$0.2014	2,986,663	A\$0.0760
2-Dec-21	31-Mar-27	A\$0.2014	2,986,663	A\$0.0780
2-Dec-21	31-Mar-27	A\$0.0965	839,385	A\$0.0900
2-Dec-21	30-Jun-27	A\$0.2014	2,986,663	A\$0.0790
2-Dec-21	30-Jun-27	A\$0.0965	839,385	A\$0.0910
5-Sep-17	5-Sep-27	A\$0.4136	10,000	A\$0.3636
2-Dec-21	30-Sep-27	A\$0.2014	2,986,663	A\$0.0810
2-Dec-21	30-Sep-27	A\$0.0965	839,385	A\$0.0920
20-Nov-20	20-Oct-27	A\$0.1519	100,000	A\$0.0950
2-Dec-21	31-Dec-27	A\$0.2014	2,986,663	A\$0.0820
2-Dec-21	31-Dec-27	A\$0.0965	839,385	A\$0.0940
2-Dec-21	31-Mar-28	A\$0.2014	2,986,663	A\$0.0840
2-Dec-21	31-Mar-28	A\$0.0965	839,385	A\$0.0950
2-Dec-21	30-Jun-28	A\$0.2014	2,986,663	A\$0.0850
2-Dec-21	30-Jun-28	A\$0.0965	839,385	A\$0.0960
2-Dec-21	30-Sep-28	A\$0.2014	2,986,663	A\$0.0860
2-Dec-21	30-Sep-28	A\$0.0965	839,385	A\$0.0970
20-Nov-20	20-Oct-28	A\$0.1519	100,000	A\$0.0990
2-Dec-21	31-Dec-28	A\$0.2014	2,986,663	A\$0.0880
2-Dec-21	31-Dec-28	A\$0.0965	839,385	A\$0.0980
2-Dec-21	31-Mar-29	A\$0.0965	839,385	A\$0.0980
2-Dec-21	30-Jun-29	A\$0.0965	839,385	A\$0.0990
2-Dec-21	30-Sep-29	A\$0.0965	839,385	A\$0.1000
20-Nov-20	20-Oct-29	A\$0.1519	100,000	A\$0.1030
2-Dec-21	31-Dec-29	A\$0.2014	2,986,663	A\$0.0920

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Grant date	Expiry date	Exercise price	Number of options	Fair value
2-Dec-21	31-Dec-29	A\$0.0965	839,385	A\$0.1010
2-Dec-21	31-Mar-30	A\$0.2014	2,986,663	A\$0.0930
2-Dec-21	31-Mar-30	A\$0.0965	839,385	A\$0.1020
2-Dec-21	30-Jun-30	A\$0.2014	2,986,662	A\$0.0940
2-Dec-21	30-Jun-30	A\$0.0965	839,385	A\$0.1020
2-Dec-21	30-Sep-30	A\$0.0965	839,385	A\$0.1030
20-Nov-20	20-Oct-30	A\$0.1519	100,000	A\$0.1070
2-Dec-21	31-Dec-30	A\$0.0965	839,385	A\$0.1040
			79,056,617	

(c) Warrants

When exercised, each warrant is convertible into one ordinary share.

Movement in unlisted share warrants:

	2022		2021		2020	
	Number of warrants	Weighted average exercise price	Number of warrants	Weighted average exercise price	Number of warrants	Weighted average exercise price
Opening balance at beginning of financial year	166,082,988	A\$0.11	40,207,472	A\$0.59	40,207,472	A\$0.59
Granted during the financial year	-	-	150,000,000	A\$0.06	-	-
Forfeited during the financial year	-	-	-	-	-	-
Exercised during the financial year	(8,000,000)	A\$0.06	-	-	-	-
Expired during the financial year	(16,082,988)	A\$0.57	(24,124,484)	A\$0.59	-	-
Closing balance at June 30	142,000,000	A\$0.06	166,082,988	A\$0.11	40,207,472	A\$0.59

The number of unlisted warrants vested and exercisable at June 30, 2022 is 142,000,000 (2021: 166,082,988).

The weighted average remaining contractual life of any unlisted warrants outstanding at the June 30, 2022 is 1.16 years (2021: 2.6 years).

Unlisted warrants issued during the year ended June 30, 2021

On August 26, 2020, shareholders approved, as consideration for Apeiron underwriting a share issue that would raise at least A\$15 million, that Apeiron would be issued 150 million warrants to subscribe for shares at A\$0.06 per share with an expiry date of August 26, 2023.

With the assistance of Apeiron a share placement was made that raised A\$15,991,634 and the warrants vested on March 3, 2021. As per IFRS 2 'Share Based Payment', the warrants have been valued based on the fair value of the services received (underwriting a share issue) which has been calculated using a risk adjusted estimated fee of 9% of the amount that was raised.

Unlisted warrants exercised during the year ended June 30, 2022

On November 11, 2021, 2,000,000 warrants were exercised at A\$0.06 per share. The share price at date of exercise was A\$0.125.

The table below lists warrants outstanding at June 30, 2022.

Grant Date	Expiry date	Exercise Price	No of options	Fair Value
26-Aug-20	26-Aug-23	A\$0.06	142,000,000	A\$0.01

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NOTE 22: RESERVES

	2022 A\$	2021 A\$
Foreign Currency Translation Reserve (a)	6,186,334	5,119,200
Share-based Payments Reserve (b)	6,337,264	6,328,691
Total Reserves	<u><u>12,523,598</u></u>	<u><u>11,447,891</u></u>

(a) Foreign Currency Translation Reserve

Exchange differences arising on translation of the foreign controlled entities are taken to the foreign currency translation reserve, as described in Note 2(i). The reserve is recognised in profit or loss when the investment is disposed of.

(b) Share-based Payments Reserve

The share-based payments reserve is used to recognise the fair value of options and warrants issued over the vesting period or the period of the Consultancy Agreement, as applicable. Further information about share-based payments is set out in Note 21.

NOTE 23: FINANCIAL INSTRUMENTS

(a) Capital Risk Management

The Group manages its capital to ensure that entities in the Group will be able to continue as going concerns whilst maximizing the return to stakeholders through the optimisation of the debt and equity balance.

During April 2021, the Group repaid in full its bank loan and equipment mortgage. The capital structure of the Group now consists of lease liabilities for rental property (Note 19) cash and cash equivalents (Note 8) and equity attributable to equity holders of the parent, comprising issued capital (Note 21), reserves (Note 22) and retained earnings.

The Group's policy is to fund the research and development activities and operations through the issue of equity and the commercialisation of intellectual property assets. Project specific borrowings are utilized where appropriate and also minor borrowings for operational assets, as required.

(b) Categories of Financial Instruments

	2022 A\$	2021 A\$
Financial Assets		
Cash and cash equivalents	33,564,857	28,499,449
Receivables	6,784,121	1,128,285
Other financial assets	119,000	554,640
	<u><u>40,467,978</u></u>	<u><u>30,182,374</u></u>
Financial Liabilities		
Trade and other payables	2,786,280	1,814,390
Lease liability – rental property	693,623	867,841
Contingent consideration at fair value	2,699,010	1,762,656
	<u><u>6,178,913</u></u>	<u><u>4,444,887</u></u>

(c) Financial Risk Management Objectives

The Board, through the Audit and Risk Management (“ARM”) Committee, is responsible for ensuring there are adequate policies in relation to risk management, compliance and internal control systems.

In summary, Group policies are designed to ensure significant strategic, operational, legal, reputational and financial risks are identified, assessed, and effectively monitored and managed in a manner sufficient for a

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company of Bionomics' size and stage of development to enable achievement of the Group's business strategy and objectives.

The Group's risk management policies are managed by the key management personnel and are reviewed by the ARM Committee according to a timetable of assessment and review proposed by that committee and approved by the Board.

(d) Market Risk

The Group's activities expose it primarily to the financial risks of changes in foreign currency exchange rates (see (e) below) and interest rates (see (f) below).

The Group may use derivative financial instruments to manage its exposure to foreign currency risk, if and when appropriate.

The Group has not entered into any interest rate derivatives.

The Group measures market risk exposures using sensitivity analysis. There has been no material change to the Group's exposure to market risks or the manner in which these risks are managed and measured.

There were no derivative financial instruments outstanding as at June 30, 2022 (2021: nil).

(e) Foreign Currency Risk Management

The Group undertakes certain transactions denominated in foreign currencies; consequently, exposures to exchange rate fluctuations arise. Exchange rate exposures are managed in accordance with established policies. The Group's exposure to foreign currency risk at the end of the reporting period, expressed in Australian dollars is as follows:

	2022 A\$	2021 A\$
Denominated in USD		
Monetary items		
Cash and cash equivalents	17,786,031	624,819
Trade and other payables	(1,298,425)	(672,353)
Contingent consideration liability	(2,699,010)	(1,762,656)
Total monetary items	<u>13,788,596</u>	<u>(1,810,190)</u>
Non-monetary items		
Goodwill	5,921,027	5,453,648
Other intangible assets	9,838,274	9,945,755
Deferred tax liability	(1,798,625)	(1,842,303)
Total non-monetary items	<u>13,960,676</u>	<u>13,557,100</u>
Total denominated in USD	<u>27,749,272</u>	<u>11,746,910</u>

Foreign Currency Sensitivity Analysis

The following table details the Group's sensitivity to a 10% increase and decrease in the Australian dollar against the US dollar. 10% is the sensitivity rate used when reporting foreign currency risk internally to key management personnel and 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 relevant currency.

For a 10% weakening of the Australian dollar against the relevant currency, there would be a comparable impact on the profit or equity with the balances being the opposite.

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	2022 A\$	2021 A\$	2020 A\$
Profit or loss (i)	1,796,641	(222,678)	(2,181,987)
Equity (ii)	18,815	3,135	10,403

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

The Group's sensitivity to foreign currency has increased as at June 30, 2022 mainly due to an increase in cash and cash equivalents that are denominated in USD as a result of the US IPO.

The sensitivity analysis may not represent the quantum of foreign exchange risk because the exposure at the end of the reporting period does not reflect the exposure during the year. Requirements change during the financial year depending on research and development.

Forward Foreign Exchange Contracts

It is the policy of the Group to enter into forward foreign currency contracts to cover specific foreign currency payments and receipts when appropriate (such as when there is a legal commitment to pay or receive foreign currency or the Executive Chairman or Chief Executive Officer has a high degree of confidence (>90%) that a foreign currency exposure will arise).

Under the Group's Treasury Policy, the Chief Financial Officer will manage the foreign exchange transaction risk adopting the following guidelines:

- Generally, hedge foreign exchange exposure identified above by entering into a forward currency contract.
- The duration of any forward currency contract(s) will approximate the period in which the net currency exposure arises.
- Recognizing the uncertainty that exists in projecting forward foreign currency flows, a maximum net foreign currency exposure position may be held at any point in time.

Due to the long-term nature of the net investment in the USD denominated wholly owned subsidiaries, the investments will not be hedged into Australian dollars, with the result that the Australian dollar value of the investments will fluctuate with the market rate through the foreign currency translation reserve.

There were no forward foreign currency contracts outstanding as at June 30, 2022 (2021: nil).

(f) Interest Rate Risk Management

The US bank loan had a variable interest rate with a floor. At June 30, 2020 the effective interest rate was 10.78% and this effective interest rate did not change during the year ended June 30, 2021 (the US borrowing was repaid in full during April 2021). The Group's other borrowings are at fixed interest rates. The Group does not use interest rate swap contracts or forward interest rate contracts.

The Group is exposed to interest rate risk only in relation to the cash and cash equivalent balances, as the interest rate floor on the US borrowing is above the LIBOR rate.

Interest Rate Sensitivity Analysis

The Group has no borrowings, other than lease liability (rental property) which is at a fixed interest rate.

(g) Credit Risk Management

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in financial loss to the Group. The Group has 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.

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The credit risk on liquid funds is limited because the counterparties are banks with high credit ratings assigned by international credit rating agencies.

The carrying amount of financial assets recorded in the financial statements, net of any allowances for losses, represents the Group's maximum exposure to credit risk.

(h) Liquidity Risk Management

Ultimate responsibility for liquidity risk management rests with the Board, which has approved an appropriate liquidity risk management framework for management of the Group's short-, medium- and long-term funding. The Group manages liquidity risk by continuously monitoring forecast and actual cash flows and matching maturity profiles of financial assets and liabilities.

(i) Liquidity and Interest Rate Risk

The following tables detail the Group's remaining contractual maturity for its financial liabilities with agreed repayment terms. The tables have been drawn up based on the undiscounted cash flows of financial liabilities based on the earliest date on which the Group can be required to pay.

To the extent that interest flows are at a variable rate, the undiscounted amount is derived from interest rate applicable at the end of the reporting period. The tables include both interest and principal cash flows.

	Weighted average effective interest rate %	Less than 1 month A\$	1 – 3 months A\$	3 – 12 months A\$	1 to 5 years A\$	5 + years A\$	Total A\$
2022							
Trade and other payables	-	2,786,280	-	-	-	-	2,786,280
Lease liability – rental property (fixed interest rate)	3.56	15,069	45,206	121,043	563,262	-	744,580
		<u>2,801,349</u>	<u>45,206</u>	<u>121,043</u>	<u>563,262</u>	<u>-</u>	<u>3,530,860</u>

	Weighted average effective interest rate %	Less than 1 month A\$	1 – 3 months A\$	3 – 12 months A\$	1 to 5 years A\$	5 + years A\$	Total A\$
2021							
Trade and other payables	-	1,814,390	-	-	-	-	1,814,390
Lease liability – rental property (fixed interest rate)	3.56	40,141	43,764	117,184	744,579	-	945,668
		<u>1,854,531</u>	<u>43,764</u>	<u>117,184</u>	<u>744,579</u>	<u>-</u>	<u>2,760,058</u>

(j) Fair Value of Financial Instruments

The Group has no financial assets that are measured at fair value and the only financial liability that is measured at fair value at the end of each reporting period is contingent consideration (Note 31). The value of financial

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assets and other financial liabilities approximate their fair value. The following table gives information about how the fair value of the financial liability is determined.

Financial Liabilities	Fair value as at 30 June 2022 A\$	Fair value as at 30 June 2021 A\$	Fair value hierarchy	Valuation technique	Significant unobservable inputs	Relationship of unobservable inputs to fair value
Contingent consideration in a business combination (Note 31)	2,699,010	1,762,656	Level 3	Discounted cash flow	Discount rate of 25% (pre-tax) and probability adjusted revenue projections.	The higher the discount rate, the lower the value. The higher the possible revenue the higher value.

Reconciliation of Level 3 fair value measurements

	2022 Contingent consideration in a business combination A\$	2021 Contingent consideration in a business combination A\$
Opening balance	1,762,656	4,975,159
Total (gain) or loss:		
- in profit or loss	936,354	(3,212,503)
Closing balance	<u>2,699,010</u>	<u>1,762,656</u>

NOTE 24: KEY MANAGEMENT PERSONNEL COMPENSATION

The aggregate compensation made to Directors and other members of key management personnel of the Group is set out below:

	2022 A\$	2021 A\$	2020 A\$
Short-term employee benefits	2,535,560	2,269,030	1,527,499
Post-employment benefits	69,039	51,982	52,106
Other long-term benefits	22,241	9,480	16,434
Share-based payments	2,819,133	1,298,208	68,518
Total key management personnel compensation	<u>5,445,973</u>	<u>3,628,700</u>	<u>1,664,557</u>

NOTE 25: COMMITMENTS FOR EXPENDITURE

(a) Operating Leases

Operating leases related to photocopier with lease term of 4 years (2021: 5 years). The following table gives information about this lease commitment, which are not included in the lease liability due to the application of the practical expedients to exclude low value leases from lease liabilities.

	2022 A\$	2021 A\$
<u>Non-cancellable Operating Lease Commitments</u>		
Within one year	5,064	5,064
Later than one year but not greater than five	13,504	19,412
Later than five years	-	-
Minimum lease payments	<u>18,568</u>	<u>24,476</u>

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(b) Rental Agreements

The Group previously sub-lets areas of its facility, which expired on July 12, 2021. Rent received from these agreements was treated according to the accounting policy outlined in Note 2(s)(iii). The following table gives information about future rental income.

<u>Future Rental Income Receivable</u>	2022 A\$	2021 A\$
Within one year	-	6,549
Later than one year but not greater than five	-	-
	<u>-</u>	<u>6,549</u>

NOTE 26: REMUNERATION OF AUDITORS

	2022 A\$	2021 A\$	2020 A\$
Audit or Review of Financial Reports			
- Group	969,726	86,500	110,000
- French subsidiaries	-	-	74,972
Other Assurance Services			
Agreed upon procedures in relation to French subsidiaries cash statement and debt statement as at February 28, 2020	-	-	27,109
	<u>969,726</u>	<u>86,500</u>	<u>212,081</u>

The auditor of Bionomics Limited is Ernst & Young (2020: Deloitte Touche Tohmatsu).

NOTE 27: CASH FLOW INFORMATION

(a) Cash and Cash Equivalents

For the purposes of the consolidated statement of cash flows, cash and cash equivalents include cash on hand and in banks, net of outstanding bank overdrafts. Cash and cash equivalents at the end of the reporting period as shown in the consolidated statement of cash flows can be reconciled to the related items in the consolidated statement of financial position as follows:

	2022 A\$	2021 A\$	2020 A\$
Cash and cash equivalents	<u>33,564,857</u>	<u>28,499,449</u>	<u>4,577,747</u>

Notes to the Financial Statements
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(b) Reconciliation of Operating Loss to Net Cash Outflow from Operating Activities

	2022 A\$	2021 A\$	2020 A\$
(Loss) for the year	(21,759,358)	(8,697,037)	(7,118,288)
Items in loss			
Depreciation and amortisation	1,109,412	1,700,878	2,443,386
Share-based payments	2,829,689	1,308,349	55,355
Loss/(Gain) on asset disposals	1,827	21,010	(173,934)
Contingent consideration – change in fair value	936,354	(3,212,503)	(4,823,874)
Amortisation of transaction costs	-	252,019	29,649
Net gain arising on modification of borrowings measured at amortised costs that were not derecognized	-	-	544,357
Accrual of final borrowing payment	-	528,819	(199,089)
Net foreign exchange differences	738,423	(1,067,746)	558,645
Loss on disposal of French operations	-	-	802,502
Interest received	(9,869)	(5,756)	(58,369)
Changes in Operating Assets and Liabilities			
(Increase)/Decrease) in receivables	(39,148)	34,078	(202,257)
(Increase)/Decrease in research and development incentive receivable	(5,791,688)	1,991,468	4,145,659
(Increase)/Decrease in other assets	(600,285)	(85,648)	348,768
(Increase) in inventory	-	-	(28,291)
Increase/(Decrease) in payables	979,902	(63,305)	127,451
Increase/(Decrease) in provisions	41,062	(55,923)	(85,407)
(Decrease) in other liabilities	-	-	(20,876)
(Decrease) in deferred tax liability	(191,808)	(187,427)	(248,580)
Net cash outflows from operating activities	<u>(21,755,487)</u>	<u>(7,538,724)</u>	<u>(3,903,193)</u>

NOTE 28: LOSS PER SHARE

	2022	2021	2020
<i>From continuing and discontinuing operations</i>			
Basic loss per share	(A\$0.02) (2 cent)	(A\$0.01) (1 cent)	(A\$0.01) (1 cent)
Diluted loss per share	(A\$0.02) (2 cent)	(A\$0.01) (1 cent)	(A\$0.01) (1 cent)

The basic and diluted loss per share amounts have been calculated using the 'Loss after income tax' figure in the consolidated statement of profit or and other comprehensive income.

	2022 A\$	2021 A\$	2021 A\$
Loss Per Share (Basic and Diluted):			
Loss after tax for the year from continuing and discontinuing operations	(21,759,358)	(8,697,037)	(7,118,288)
Loss after tax for the year from continuing operations	(21,759,358)	(8,697,037)	(5,818,975)

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	2022 number	2021 number	2010 number
Weighted Average Number of Ordinary Shares - Basic			
Weighted average number of ordinary shares used in calculating basic loss per share:	1,353,350,744	779,941,036	544,871,870
Weighted Average Number of Ordinary Shares – Diluted			
Weighted average number of ordinary shares used in calculating basic loss per share:	1,353,350,744	779,941,036	544,871,870
Shares deemed to be issued for no consideration in respect of employee options	31,065,272	20,056,450	5,296,550
Potential ordinary shares which are anti-dilutive and excluded	(31,065,272)	(20,056,450)	(5,296,550)
Shares deemed to be issued for no consideration in respect of warrants	142,000,000	166,082,988	40,207,472
Potential ordinary shares which are anti-dilutive and excluded	(142,000,000)	(166,082,988)	(40,207,472)
Weighted average number of ordinary shares used in the calculation of diluted loss per share	<u>1,353,350,744</u>	<u>779,941,036</u>	<u>544,871,870</u>

The following potential ordinary shares are anti-dilutive and are therefore excluded from the weighted average number of ordinary shares for the purposes of diluted loss per share.

	2022 number	2021 number	2020 number
Employee options	31,065,272	20,056,450	5,296,550
Warrants	142,000,000	166,082,988	40,207,472

NOTE 29: RELATED PARTY TRANSACTIONS

(a) Parent Entity

The immediate parent and ultimate controlling party of the Group is Bionomics Limited. Interests in subsidiaries are set out in Note 12.

(b) Key Management Personnel

Disclosures relating to compensation of key management personnel are set out in Note 24 and the Directors' Report.

(c) Loans to Directors and Other Key Management Personnel

There were no loans to any Directors of the Company or other key management personnel of the Group during the financial year ended 30 June 30, 2022 (2021: Nil).

(d) Shares Issued to Apeiron Investment Group Limited ("Apeiron") and Apeiron Presight Capital Fund II LP ("Presight"), (Director related entities).

During the year ended June 30, 2022, 7,287,480 shares were issued to Apeiron, and 109,311,660 shares were issued to Presight at \$0.09645 per share as a result of the US IPO (2021: 54,333,000 shares at \$0.04 per share issued to Apeiron as a result of share placements and 26,222,424 shares issued to Apeiron at \$0.145 per share as a result of the Rights Issue that occurred).

(e) Shares Issued to BVF Partners (a Director related entity) ("BVF")

During the year ended June 30, 2022, 14,574,780 shares at A\$0.09645 per share were issued to BVF as a result of the US IPO (2021: 10,864,351 shares at A\$0.04 per share and 36,115,866 shares at A\$0.145 per share as a result of the rights issue that occurred).

(f) Shares Issued to Directors

No shares were issued to Directors during the year ended June 30, 2022. During the year ended June 30, 2021 shares were issued to the following Directors as a result of the rights issue that occurred:

- 15,949 shares at A\$0.04 per share to Mr Peter Turner; and

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- 15,949 shares at A\$0.04 per share and 35,990 shares at \$0.145 per share to Mr David Wilson.

(g) Shares Issued to Other Key Management Personnel

On August 28, 2020, 314,246 fully paid shares were issued to Mr Jack Moschakis and 109,986 fully paid shares were issued to Ms Liz Doolin as part of their bonus for the year ended June 30, 2020, based on the average 5-day VWAP for the period to August 28, 2020.

(h) Share Options Issued to Directors and Other Key Management Personnel

During the year ended June 30, 2022 share options were issued to Dr Errol De Souza, details about these share options are set out in Note 21(b) (i) to the Financial Statements. (2021: share options were issued to Dr Errol De Souza, Dr Jane Ryan, Mr Jack Moschakis and Ms Liz Doolin, details about these share options are set out in Note 21(b) (ii) to the Financial Statements).

(i) Warrants Issued to Apeiron (a director related entity)

On August 26, 2020, shareholders approved, as consideration for Apeiron underwriting a share issue that would raise at least A\$15 million, that Apeiron would be issued 150 million warrants to subscribe for shares at A\$0.06 per share with an expiry date of 23 August 2023, details about these warrants are set out in Note 21(c) to the Financial Statements.

(j) Memorandum of Understanding (“MOU”) with EmpathBio Inc (“EmpathBio”)

On February 17, 2021, the Company entered into a MOU with EmpathBio Inc, a wholly owned subsidiary of Germany-based CNS clinical development company, atai Life Sciences NV (“atai”), what is a related party of Apeiron (a director related entity), when the MOU was signed. Under the MOU, the Company and EmpathBio propose to collectively explore a combination drug treatment regimen with Bionomics’ BNC210 and EmpathBio’s 3,4-Methylenedioxymethamphetamine (MDMA) derivative EMP-01. The parties will explore whether the different mechanisms of action of EMP-01 and BNC210 may offer the potential for developing an improved treatment regimen for the treatment of PTSD.

NOTE 30: CONTINGENT CONSIDERATION

During the year ended June 30, 2013, the Company acquired Eclipse Therapeutics, Inc (Eclipse) into its wholly owned subsidiary, Bionomics Inc. Part of the consideration are potential cash earn-outs to Eclipse security holders based on achieving late-stage development success or partnering outcomes of the Eclipse asset that was acquired. This liability is recorded at fair value; see Note 23(j), for information about the calculation of the fair value. Due to changes in the projected inputs, being the timing and quantum of expected cash outflow, which are in USD dollars, the liability increased by A\$936,354 at June 30, 2022 (decreased by A\$3,212,503 at June 30, 2021). Inputs used are based on the anticipated amounts and timing of potential milestone and royalty payments from licensing agreement with Carina Biotech Pty Ltd (Carina). International financial reporting standards required that in a “business combination” (the Company acquiring Eclipse) any contingent consideration liability at acquisition date needs to be recorded at the fair value and subsequent changes in the fair value is recognized in profit or loss, but any contingent assets at acquisition date are not allowed to be recorded. The Company has a contingent asset (the expected payments to be received from Carina) at June 30, 2022 which is greater than the contingent consideration liability.

	2022 A\$	2021 A\$
Opening balance	1,762,656	4,975,159
Change in fair value	936,354	(3,212,503)
Closing balance	<u>2,699,010</u>	<u>1,762,656</u>

NOTE 31: CONTINGENT LIABILITIES

- In January 2012, the Company entered into a research and license agreement with Ironwood Pharmaceuticals, Inc., or Ironwood, pursuant to which Ironwood was granted worldwide development and commercialization rights for BNC210. In November 2014, the parties mutually agreed to terminate this license agreement, reverting all rights to BNC210 back to the Company. The sole obligation to Ironwood is to pay Ironwood low single digit royalties on the net sales of BNC210, if commercialized. It is not practicable to estimate the future payments of any such royalties that may arise due to the stage of development of BNC210.

Notes to the Financial Statements

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- The Group has provided a restricted cash deposit of A\$119,000 (2021: A\$554,640) as security for an unconditional irrevocable bank guarantee as a rent guarantee of \$119,000 (2021: A\$554,640) to the landlord of the Company's leased office premises.
- The Group has a consultancy agreement with Dr Errol De Souza who is paid US\$43,750 per month (plus reimbursement of health care benefits of up to US\$22,000 per year), plus a short-term incentive/bonus potential of 60% of fixed remuneration as assessed by the independent non-Executive directors against agreed financial, strategic and operational targets, for performance exceeding such applicable performance criteria the annual bonus may be increased up to 100% of Base Salary.
- The Group has a contingent liability in relation to this consultancy agreement, where the arrangement is terminated by the Company without cause, redundancy or resignation for good reason, in that the Company will:
 - pay severance of twelve 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, and
 - 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.
- Any termination benefits in excess of the limits in the Corporations Act are subject to shareholder approval.

NOTE 32: EVENTS OCCURRING AFTER REPORTING DATE

On July 15, 2022, the Company issued 7,700,000 share options to subscribe for 7,700,000 shares at \$0.0543 per share, under the Employee Equity Plan that was approved by shareholders at the Annual General Meeting held on December 2, 2021, including 7,500,000 share options that were issued to key management personnel (KMP). 25% of the Options vest at the end of 12 months following the Offer Date (July 8, 2022), and 75% vest in 12 substantially equal instalments (6.25%) on the last day of each calendar quarter over the 4-year period following the end of the initial 12 months following the Offer Date. The share options expire on the date that is 5 years following each vesting date. Details of share options that were issued to the KMPs are set out below:

KMP	Number
Mr Adrian Hinton	2,000,000
Mr Connor Bernstein	3,500,000
Ms Liz Doolin	2,000,000

On August 5, 2022, the Company received A\$2,085,453 research and development tax incentive refund relating to the financial year ended June 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.

There are no other matters or circumstances that have arisen since the end of the financial year which significantly affect or may significantly affect the results of the operations of the Group.

NOTE 33: IMPACT OF COVID-19

The Board and Management have considered the impact of COVID-19 on the Company's operations and financial performance. Overall, operations for the year ended June 30, 2022 have not been materially affected by the COVID-19 pandemic.

The clinical trials for PTSD and SAD started in US during July 2021 and January 2022, respectively and to date have not been materially affected by the COVID-19 pandemic except for postponing screening and enrolment of potential participants into the trial. However, there may be disruptions caused by COVID-19 pandemic that may result in increased costs and delays in completing the PTSD and SAD clinical trials. The Company is working closely with its clinical partners and has taken the necessary steps to allow for adjustments in the clinical trials protocol should they be required due to restrictions that may be imposed during the COVID-19 pandemic.

The Company cannot predict the scope and severity of any further disruptions as a result of COVID-19 or its impact on the business. Unforeseen disruptions to the business or any of the third parties we use, including the collaborators, contract organisations, manufacturers, suppliers, clinical trial sites, and regulators could materially and negatively impact our ability to conduct business in the manner and on the timelines presently planned. The extent to which

Notes to the Financial Statements
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COVID-19 pandemic may continue to impact the business and financial performance will depend on future developments, which are highly uncertain and cannot be predicted with confidence. Currently, the Company is unable to determine the extent of the impact of the pandemic on the clinical trials, operations and financial performance going forward. These developments are highly uncertain and unpredictable and may materially adversely affect the Company's future operating results and financial position.

NOTE 34: DISCONTINUED OPERATIONS

On March 3, 2020, the Company sold its two wholly owned French subsidiaries, Neurofit SAS and PC SAS, which carried out all the Group's contract service business. The sale price of Euro 1,790,029 is the amount of intercompany debt owed by the Company to the subsidiaries for scientific research conducted by them on the Company's drug candidates and this debt was assumed by the purchaser upon acquisition of the two companies.

Costs incurred by the Company in relation to this transaction were A\$207,143. The disposal of the contract service operations is consistent with the Group's long-term policy to focus its activities on the clinical trial of BNC210 for the treatment of PTSD.

(a) Analysis Assets and Liabilities Over Which Control Was Lost

	Year ended June 30, 2020 A\$
<u>Current assets</u>	
Cash and cash equivalents	800,849
Trade and other receivables	1,047,259
Research and development incentives receivable	770,054
Inventories	692,832
Other assets	85,115
<u>Non-current assets</u>	
Property, plant and equipment	2,006,977
Right-to-use asset – rented property	1,424,365
Other intangible assets	574
<u>Current liabilities</u>	
Trade and other payables	(2,312,900)
Lease liability – rented property	(161,723)
Provisions	(446,148)
Other liabilities	(204,860)
<u>Non-current liabilities</u>	
Other payables	(816,663)
Lease liability – rented property	(1,278,599)
Deferred tax liabilities	(514,962)
Net assets disposed of	<u>1,092,170</u>

(b) Loss on Disposal of Subsidiary

	2020 A\$
Net assets disposed of	(1,092,170)
Costs relating to the disposal incurred by the Company	(207,143)
Loss on disposal	<u>(1,299,313)</u>

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(c) Net Cash Outflow on Disposal of Subsidiaries

	2020
	A\$
Cash and cash equivalent balances disposed of	(800,849)
Costs relating to the disposal incurred by the Company	(207,143)
Net cash outflow	<u>(1,007,992)</u>

(d) Analysis of (Loss)/Profit for the Year from Discontinued Operations

The combined results of the discontinued operation (contract service business) included in the loss for the year ended June 30, 2020 are set out below.

	2020
	A\$
Revenue	3,422,584
Other income	391,505
	<u>3,814,089</u>
Expenses	(4,242,502)
Loss before income tax benefit	(428,413)
Income tax benefit	40,968
	<u>(387,445)</u>
Loss on disposal of operations including a cumulative gain of A\$496,811 recycled from foreign currency translation reserve to profit and loss	(911,868)
Attributable income tax expenses	-
	<u>(911,868)</u>
Loss from discontinued operations	<u>(1,299,313)</u>

(e) Analysis of Cash Flows from Discontinued Operations

The cash flows from discontinued operations for the year ended June 30, 2020 are set out below:

Cash flows for the year from discontinued operations

	2020
	A\$
Inflows from operating activities	470,767
Outflows from investing activities	(7,704)
Outflows from financing activities	(100,489)
Net cash flow	<u>362,574</u>

DESCRIPTION OF SECURITIES

General

The following description of the ordinary shares of Bionomics Limited (the “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 incorporated by reference as an exhibit to our Annual Report on Form 20-F (our “Constitution”). The “Company,” “we,” “us,” or “our” refer to Bionomics Limited and its consolidated subsidiaries.

Subject to restrictions on the issue of securities in our Constitution, the Corporations Act 2001 (Cth) (the “Corporations Act”) and the Australian Securities Exchange (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.

American Depositary Shares (“ADSs”) representing one hundred eighty (180) Ordinary Shares of Bionomics Limited (the “shares”) are listed and traded on The Nasdaq Global Market and, in connection with this listing (but not for trading), the shares are registered under Section 12(b) of the Exchange Act. This exhibit contains a description of the rights of (i) the holders of shares and (ii) ADS holders. Shares underlying the ADSs are held by Citibank, N.A., as depositary, and holders of ADSs are not be treated as holders of the shares. 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.

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, and is qualified in its entirety by reference to the complete text of our Constitution, a copy of which is on file with the Securities and Exchange Commission.

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 the Australian Securities and Investments Commission (“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.

Shares

Type and Class of Securities (Item 9.A.5 of Form 20-F)

Our outstanding share capital consists of only one class of Ordinary Shares. The concept of par value is not recognized under Australian law. The number of shares that have been issued as of the last day of the financial year ended June 30, 2022 is given in Note [21] 'Issued Capital' in the Notes to Consolidated Financial Statements of the Form 20-F for the financial year ended June 30, 2022 (the "Form 20-F"). Bionomics Limited's shares are uncertificated.

Preemptive Rights (Item 9.A.3 of Form 20-F)

Ordinary shareholders do not have preemptive rights.

Limitations or Qualifications (Item 9.A.6 of Form 20-F)

Not applicable. See "Rights and Restrictions on Classes of Shares" below which describes how directors may issue preference shares.

Other Rights (Item 9.A.7 of Form 20-F)

Not applicable.

Rights and Restrictions on Classes of Shares (Item 10.B.3 of Form 20-F)

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, 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.

Dividend Rights

Under the Corporations Act, a company must not pay a dividend unless (a) the company's assets exceed its liabilities immediately before the dividend is declared and the excess is sufficient for the payment of the dividend; (b) the payment of the dividend is fair and reasonable to the company's shareholders as a whole; and (c) the payment of the dividend does not materially prejudice the company's ability to pay its creditors. Subject to this requirement, 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 or required under the Constitution or the Corporations Act (including any modifications or amendments). 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.

Under Australian law, an ordinary resolution is passed if a majority of the votes cast on the resolution (in person or by proxy) by members entitled to vote on the resolution are in favor of the resolution. Under Australian law, a special resolution is passed if at least 75% of the votes cast on the resolution (in person or by proxy) are in favor of the resolution.

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. Under the Corporations Act, redeemable preference shares may only be redeemed if those preference shares are fully paid-up and payment in satisfaction of redemption is out of profits or the proceeds of a new issue of shares made for the purposes of the redemption.

Variation or Cancellation of Share Rights

Subject to Corporations Act, the ASX Listing Rules and the terms of issue of shares of that class, the rights and privileges 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 compliance with the Corporations Act and 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.

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.

Requirements to Change the Rights of Holders of Ordinary Shares (Item 10.B.4 of Form 20-F)

See “Rights and Restrictions on Classes of Shares—Variation and Cancellation of Share Rights” above.

Limitations on the Rights to Own Shares (Item 10.B.6 of Form 20-F)

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\$1,250 million for foreign acquirers from all other countries (and assuming we are not considered a sensitive business).

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.

Provisions Affecting Any Change of Control (Item 10.B.7 of Form 20-F)

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.

Ownership Threshold (Item 10.B.8 of Form 20-F)

There are no specific 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 Corporation Act) of 5% or more of the votes in our Ordinary Shares), at which point the shareholder is 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. As a U.S. public company, our shareholders are also subject to disclosure requirements under U.S. securities laws.

Differences Between the Law of Different Jurisdictions (Item 10.B.9 of Form 20-F)

See “Rights and Restrictions on Classes of Shares” above. The Australian law applicable to our Constitution is not significantly different than a U.S. company’s charter documents except we do not have a limit on our authorized share capital, as the concept of par value is not recognized under Australian law.

Changes in Capital (Item 10.B.10 of Form 20-F)

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, privileges or conditions or with 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 the 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.

American Depositary Shares (Items 12.D.1 and 12.D.2 of Form 20-F)

Citibank, N.A. had 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 had 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 is 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 are 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 are 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 are 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 are 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.

Exh. 2.3-8

The registration of the Ordinary Shares in the name of the depository bank or the custodian shall, to the maximum extent permitted by applicable law, vest in the depository 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 depository 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 depository 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 depository 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 depository 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 depository 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 depository 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 depository 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 depository 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 depository bank and we will assist the depository 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 depository bank; or
- The depository 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 depository bank in advance. If it is practicable and if we provide all of the documentation contemplated in the deposit agreement, the depository 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 depository 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 depository 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 depository 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 depository 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 depository bank may not lawfully distribute such property to you, the depository 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

The Ordinary Shares were deposited by us with the custodian. Upon receipt of confirmation of such deposit, the depository bank issued ADSs.

The depository 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 depository 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 depository 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 depository 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 depository 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 are entitled to transfer, combine or split up your ADRs and the ADSs evidenced thereby. For transfers of ADRs, you 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 are 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 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.

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 are 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 maintains 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 maintains 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 are not 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.

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 are 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, 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.

Exh. 2.3-16

COMMERCIAL IN CONFIDENCE

23 July 2022

Mr Adrian Hinton
15 Silver Crescent
GRANGE SA 5022

Dear Adrian

Amendment to your Consultancy Agreement dated 18 March 2019

I write to confirm that the Company would like to extend the term of your consultancy services for a period of 1 July 2022 to 30 June 2023 with the following amendment:

- Schedule 3 – Fees, in the Agreement will be replaced with the following:

“The fee for the Services are to be calculated as follows:

- a) \$21,000 per month or \$252,000 per year, payable by invoicing the Company at the end of each month during the provision of Executive Services.
- b) Bonus target of 20% of \$252,000 with 50% based on Company Goals and 50% based on Personal Goals”

Please confirm your agreement to this amendment on the terms outlined in this letter by signing and dating this letter and returning it to me at your earliest convenience.

Yours sincerely

/s/ Errol De Souza
Errol De Souza
Executive Chairman

s/s Adrian Hinton
Mr Adrian Hinton

26/7/22
Date

COMMERCIAL IN CONFIDENCE

1 July 2022

Liz Doolin
50 Devereux Road
HAZELWOOD PARK SA 5066

Dear Liz

After completing several reviews at the end of the financial year, including your salary, I am pleased to advise that your Total Remuneration Package will increase, effective from 1 July 2022 from \$230,000.00 per annum to \$243,000.00 per annum. Out of this package, superannuation payments will be made by Bionomics to cover its obligations under the Superannuation Guarantee (Administration) Act 1992.

The Nomination & Remuneration Committee has also recognised your commitment over the last year and I am pleased to advise that a bonus of \$34,500 will be paid to you. The bonus amount will appear in your July pay and will be taxed accordingly.

Further to this, the Board has also approved the issue of 2,000,000 bonus options to you in recognition of the company's achievements, and your personal goals in the 2021/2022 financial year. The offer letter for the options will be forwarded to you separately.

Thank you for your loyalty, support and continued contribution to Bionomics.

Yours sincerely

/s/ Adrian Hinton
Adrian Hinton
Acting Chief Financial Officer

Bionomics Limited ABN 53 075 582 74031
Dagleish Street Thebarton SA Australia 5031 **Phone** 61 8 8354 6100 **Fax** 61 8 8354 6199 **Email** info@bionomics.com.au
website www.bionomics.com.au

Exh. 4.18-1

BIONOMICS LIMITED

CONNOR B. BERNSTEIN, JB STRATEGY PARTNERS LLC

CONSULTANCY AGREEMENT

Exh. 4.19-1

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Exh. 4.19-3

CONSULTANCY AGREEMENT

THIS AGREEMENT is made on 1 April 2021 between:

1. **BIONOMICS LIMITED** ABN 53 075 582 740, of 200 Greenhill Road, Eastwood, South Australia, 5063 (“**Bionomics**”); and
2. **THE CONSULTANT** named in item 1 of Schedule 1 (“**the Consultant**”).

RECITALS

- A. Bionomics requires the Consultant to provide certain professional consultancy services (“**the Services**”) to Bionomics.
- B. The Consultant has agreed to provide the Services to Bionomics upon the terms and conditions set out in this Agreement.

OPERATIVE PART:

1. DEFINITIONS AND INTERPRETATION

1.1. Definitions

In this Agreement, unless a contrary intention appears:

“**Business Day**” means a day on which banks are open for normal trading business in Adelaide, South Australia, and excludes all Saturdays, Sundays and public holidays.

“**Commencement Date**” means the date specified in item 2 of Schedule 1.

“**Expiry Date**” means the date specified in item 3 of Schedule 1.

“**Intellectual Property Rights**” means any industrial and intellectual property rights including, without limitation, any rights in respect of or in connection with any confidential information, know-how, copyright, patents, trademarks, design rights, reports, drawings, specifications or eligible layout rights and including any rights to apply for registration of such industrial and intellectual property rights.

“**Services**” means the services specified in Schedule 2.

1.2. Interpretation Rules

In this Agreement, unless a contrary intention appears:

- (a) a reference to this Agreement is a reference to this Agreement as amended, varied, supplemented or replaced from time to time;
- (b) words or expressions:
 - (i) importing the singular include the plural and vice versa;
 - (ii) importing a gender include the other genders;
 - (iii) denoting individuals include corporations, partnerships, unincorporated bodies, authorities and instrumentalities;
- (c) a reference to a party to this Agreement includes that party's executors, administrators, successors and permitted assigns;

- (d) where a word or phrase is defined or given a meaning, any other part of speech or grammatical form of that word or phrase has a corresponding meaning;
- (e) a reference to a clause or schedule is a reference to a clause or schedule of this Agreement;
- (f) a reference to \$ or dollars is a reference to Australian dollars;
- (g) headings are for convenience only and do not affect the interpretation of this Agreement;
- (h) a provision of this Agreement must not be construed to the disadvantage of a party merely because that party was responsible for the preparation of the Agreement or the inclusion of the provision in the Agreement; and
- (i) the Schedules and Recitals to this Agreement form part of this Agreement and have effect as if set out in full in this Agreement.

2. APPOINTMENT OF CONSULTANT

2.1. Appointment

As and from the Commencement Date, Bionomics appoints the Consultant to provide the Services as required by Bionomics from time to time.

2.2. Term

Subject to clause 2.3, this Agreement has effect from the Commencement Date and, unless terminated earlier in accordance with the provisions of this Agreement, remains in force until the Expiry Date.

2.3. Extension of Term

If, prior to the Expiry Date, the parties agree in writing that this Agreement is to have effect for a mutually agreed period after the Expiry Date, then this Agreement, unless terminated earlier in accordance with the provisions of this Agreement, remains in force until the expiration of that further period.

2.4. Nature of Relationship

The Consultant will provide the Services as an independent contractor and not as an agent, employee, servant or partner of Bionomics. The Consultant has no authority to bind Bionomics in any way and must not hold themselves out as having authority to bind Bionomics or as being an agent, employee, servant or partner of Bionomics.

2.5. Exclusivity

This Agreement does not grant the Consultant an exclusive right to perform any or all of the Services described in Schedule 2 during the term of this Agreement. Bionomics reserves the right to employ or retain any other consultant to perform those Services during the term of this Agreement or to perform the services itself.

3. CONSULTANCY FEE AND EXPENSES

3.1. Fee

The consideration for the Services provided to Bionomics pursuant to this Agreement will be calculated on the basis described in Schedule 3.

3.2. Expenses

The Consultant is entitled to recover from Bionomics all expenses reasonably incurred in the provision of the Services, provided that it has received Bionomics' prior written authorisation for the incurring of those expenses (including travel expenses).

3.3. Billing

The Consultant will invoice Bionomics at monthly intervals for Services performed over the previous month. Each invoice must set out details of expenses incurred in that period, the date on which the Services were provided, the nature of those Services and the identity of the person who performed them. The invoices must be sent to accountspayable@bionomics.com.au for processing.

3.4. Payment

- (a) Bionomics must pay the Consultant the amount invoiced within 30 days of receipt of the invoice.
- (b) There shall be added to any charges or fees payable by Bionomics under this Agreement amounts equal to any and all applicable taxes, however designated, incurred as a result of or otherwise in connection with this Agreement or the Services including but not limited to all taxes, duties or other imposts, levied by any taxing body, but excluding taxes based upon the net income of the Consultant.
- (c) If the Consultant is required to account for GST in respect of any supply of goods or services or any other supply to Bionomics under this Agreement then the fee in respect of those supplies will be increased by the amount of the GST that the Consultant will be required to account for as a result of the supplies provided that the Consultant provides Bionomics with a tax invoice (within the meaning of the Commonwealth taxation legislation) in respect of any such supply.

3.5. Withholding Payment

In the event of any dispute with regard to a portion of an invoice, the undisputed portion will be paid by Bionomics in accordance with this clause 3.

4. CONSULTANT'S WARRANTIES

4.1. Service Standards

The Consultant warrants that the Services will be:

- (a) performed with all due expedition and at the direction and to the reasonable satisfaction of Bionomics;
- (b) provided with all due care and skill;
- (c) performed to the highest professional standards; and
- (d) performed in compliance in all respects with all laws of the Commonwealth and the State of South Australia as they apply from time to time.

4.2. Intellectual Property Rights

The Consultant warrants that in performing its obligations under this Agreement, including giving effect to the assignment of Intellectual Property Rights pursuant to clause 8, it will not infringe the Intellectual Property Rights of any third party.

5. CONSULTANT'S OBLIGATIONS

5.1. Records

The Consultant must:

- (a) keep full and proper written records of work performed under and in accordance with this Agreement;
- (b) provide copies of such records to Bionomics, or allow Bionomics to inspect such records, upon request by Bionomics; and

- (c) provide such further information in relation to the provision of Services by the Consultant as Bionomics may, at its cost, from time to time reasonably require.

5.2. Service Specifications and Variations

Bionomics must approve any variations to the Services to be performed under this Agreement.

5.3. Other Obligations

The Consultant will at all times during the term of this Agreement ensure that the Consultant does not purport to act as an agent for Bionomics to pledge the credit of Bionomics or otherwise bind Bionomics except to the extent to which such conduct has been expressly authorised by Bionomics.

6. CONFIDENTIALITY

- (a) The Consultant must keep the contents and subject matter of this Agreement strictly confidential.
- (b) Save for any information or data which is known to or in the possession or control of the Consultant, or public knowledge, or where the Consultant is required by law to disclose any confidential information to a third person (including any government, regulatory body or stock exchange), the Consultant will keep any information or data coming to it by virtue of being a party to this Agreement strictly confidential and must not use or disclose such information or data except for a purpose contemplated by this Agreement.
- (c) The Consultant's obligations under this clause 6 will survive termination of this Agreement.

7. INTELLECTUAL PROPERTY

7.1. Bionomics' Rights

Bionomics will be solely and absolutely entitled to any Intellectual Property Rights derived from any concept, idea, work, process or item created, developed or discovered by, or under the direction or oversight of, the Consultant in the course of performing the Services and the parties agree that any such Intellectual Property Rights will, without the need for any further action, vest in Bionomics upon their creation.

7.2. Assistance to be Provided

The Consultant must do all things which Bionomics may reasonably require in order to perfect, protect or exploit Bionomics' title to any of the Intellectual Property Rights referred to in clause 7.1. Bionomics will reimburse the Consultant for all reasonable costs and expenses incurred by the Consultant in taking such action.

7.3. Vesting of Intellectual Property Rights

If any Intellectual Property Rights to which Bionomics is entitled pursuant to clause 7.1 do not vest in Bionomics upon their creation, the Consultant will do all things which Bionomics may reasonably require in order to assign those Intellectual Property Rights to Bionomics.

7.4. Maintenance of Integrity

The Consultant will not do anything or aid or assist any other person to do anything which would infringe upon, harm, challenge, deny, question or contest the validity of the Intellectual Property Rights, or their ownership by Bionomics. If the Consultant learns of any actual or threatened infringement or piracy of Bionomics' Intellectual Property Rights, the Consultant must immediately notify Bionomics of such infringement or piracy.

7.5. Unauthorised Use

The Consultant will not use Bionomics' letterhead, Bionomics' name or Bionomics' resources for any purpose other than the performance of the Consultant's duties under this contract without the express authorisation of Bionomics.

7.6. Survival of Obligations

The Consultant's obligations under clauses 7.1, 7.2, 7.3 and 7.5 will survive the expiration or termination of this Agreement.

8. TERMINATION

8.1. Termination by Bionomics

- (a) Subject to clause 8.1(b), Bionomics may terminate this Agreement for any reason whatsoever by providing the Consultant with one month's written notice. This right is in addition to, and not exclusive of, rights and remedies provided by law.
- (b) Bionomics may terminate this Agreement with immediate effect if the Consultant has failed to perform or observe any of the obligations and undertakings to be performed under this Agreement and Bionomics has given notice to the Consultant that it requires the default to be remedied within 7 days and the claimed default has not been remedied within that 7 day period.

8.2. Termination by Consultant

The Consultant may terminate this Agreement for any reason whatsoever by giving Bionomics one month's written notice.

8.3. Payments

Where this Agreement is terminated by Bionomics under clause 8.1 (a), the Consultant will be entitled to receive remuneration pursuant to clause 3 in respect of Services properly performed, and expenses incurred, up to the date of termination, including the target bonus in Schedule 3(c) earned for the period up to the termination date.

Where the Agreement is terminated by Bionomics under clause 8.1(b) or the Consultant under clause 8.2, the Consultant will be entitled to receive remuneration pursuant to clause 3 in respect of Services properly performed, and expenses properly incurred, up to the date of termination.

8.4. Consequences of Termination or Expiration

Upon the termination or expiration of this Agreement, each party will deliver to the other:

- (a) all property of the other in its possession or control; and
- (b) all Confidential Information of the other party, howsoever stored.

Upon the termination or expiration of this Agreement the Consultant will cease performing the Services.

9. INDEMNITY

- (a) The Consultant must indemnify and keep indemnified Bionomics, its officers, employees, agents, licensees, successors and assigns from and against all and any damages, liabilities, judgment, losses, costs and expenses, including legal fees, suffered or incurred by Bionomics, its officers, employees, agents, licensees, successors and assigns arising from any claim, suit, action or proceeding by any person as a result, whether directly or indirectly of:
 - (i) any breach of this Agreement by the Consultant;
 - (ii) any claim by any person that the rights granted to Bionomics under this Agreement infringe the rights, including the Intellectual Property Rights, of any person.
- (b) The Consultant will at all times indemnify Bionomics, its successors, licensees and assigns from and against any and all damages, liabilities, judgment, losses, costs and expenses, including legal fees, arising

out of any breach by the Consultant of any provision of this Agreement, provided that Bionomics will notify the Consultant in writing immediately it becomes aware of any such claim or action, and no such claim or action will be compromised or settled without consultation with the Consultant.

10. NOTICE

10.1. How Notices Must Be Given

A notice, approval, direction, consent, offer, demand or other communication in connection with this Agreement must be:

- (a) in writing;
- (b) signed by an authorised officer of the relevant party; and
- (c) given to the recipient party:
 - (i) by hand delivery;
 - (ii) by pre-paid mail sent to that party; or
 - (iii) by facsimile transmission to that party.

10.2. Where Such Notices Must Be Sent

For the purposes of clause 10.1:

- (a) deliveries must be delivered to the address of the recipient party set out below;
- (b) mail must be sent to the address of the recipient party set out below;
- (c) facsimile messages must be transmitted to the facsimile number of the recipient party set out below; and in each case must be marked for the attention of the person specified below in relation to the recipient party:

Name:	Bionomics Limited
Address:	200 Greenhill Road Eastwood SA 5063
Attention:	Mr Errol De Souza
Facsimile:	+61 8 8354 6181
Name:	JB Strategy Partners LLC c/o Mr Connor B. Bernstein
Address:	1257 Crompton Road, Redwood City, CA 94061, USA
Email:	ConnorBBernstein@gmail.com

10.3. Change of Details

- (a) A party may from time to time change any of the details specified above by not less than five (5) Business Days' notice to each other party.

(b) If details are changed in accordance with this clause, this clause applies as if those changed details were set out above.

10.4. Proof of Notices

(a) Proof of posting by pre-paid mail of a notice in accordance with clauses 10.1 and 10.2 is proof of receipt of such notice on the second clear Business Day after posting.

(b) Proof of transmission by facsimile of a notice in accordance with clauses 10.1 and 10.2 is proof of legible receipt on the date of transmission, but if a transmission is not made on a Business Day or not made before 4.00 pm, then it will be deemed to have been received at 10.00 am on the next Business Day after transmission.

11. MISCELLANEOUS PROVISIONS

11.1. No Waiver

A party's failure or delay to exercise a power or right is not a waiver of that right, and the exercise of a power or right does not preclude the future exercise of that or any other power or right.

11.2. Entire Agreement

This Agreement is the entire agreement between the parties as to its subject matter and supersedes all prior agreements, representations, conduct and understandings.

11.3. Amendments

No amendment of, nor addition to, this Agreement is binding unless it is in writing and executed by the parties to this Agreement.

11.4. Severance

If any provision of this Agreement is held by a court to be void or unenforceable in whole or in part, the Consultant and Bionomics agree that the relevant provision or part of the provision shall be severed from this Agreement and that the remainder of this Agreement shall continue to be valid and enforceable.

11.5. Law

This Agreement is governed by the law of the State of South Australia and the parties submit to the non-exclusive jurisdiction of the courts of South Australia.

11.6. No Assignment

The Consultant may not assign or subcontract its rights and obligations under this Agreement without the prior written consent of Bionomics. Bionomics may assign or subcontract its rights and obligations under this Agreement.

EXECUTION

EXECUTED by the parties as an Agreement.

SIGNED for and on behalf of
BIONOMICS LIMITED by its duly
authorised officer

)
)
) /s/ Errol de Souza
.....
Signature of Authorised Person

Executive Chairman
Office Held

Errol B De Souza
Name of Authorised Person

SIGNED for and on behalf of
THE CONSULTANT
MR CONNOR B BERNSTEIN

) /s/ Connor Bernstein
)
) Signature of Consultant

SCHEDULE 1

Item 1 Consultant

Name: Mr Connor B Bernstein

JB STRATEGY PARTNERS LLC

Address: 1257 Crompton Road, Redwood City, CA 94061, USA

Telephone: 0011 1 (831) 246 3642

Email: ConnorBBernstein@gmail.com

Item 2 Commencement Date

The Commencement Date shall be 1 April 2021

Item 3 Expiry Date

The Expiry Date shall be the 31 March 2022

Exh. 4.19-12

SCHEDULE 2

SERVICES

The Consultant will devote approximately 80% of his time to perform the duties of Vice President of Strategy & Corporate Development. Those duties shall be as directed by the Executive Chairman and will include:

- work closely with the Executive Chairman to develop and execute on the Corporate and Finance Strategy for the Company;
- coordinate internal efforts related to investor and public relations including external discussions with investment banks, analysts, investment funds and shareholders;
- coordination of all activities (including legal and audit) in conjunction with CFO and Executive Chairman related to exploration and execution as necessary for listing on Nasdaq;
- coordination of activities related to corporate development including in-licensing and out-licensing; and
- such other duties and responsibilities as the Executive Chairman may request from time to time; collectively referred to as **Executive Services**.

Exh. 4.19-13

SCHEDULE 3

FEES

The Fee shall for the provision of Executive Services shall be;

- (a) USD 15,000 per month payable by invoicing the Company at the end of each month during the provision of the Executive Services.

Exh. 4.19-14



COMMERCIAL IN CONFIDENCE

27 July 2022

Mr Connor B Bernstein
JB STRATEGY PARTNERS LLC
552 Hauth Lane
Walnut Creek, CA 94567, USA

Dear Connor

Amendment to your Consultancy Agreement dated 1 April 2021

I wish to confirm that the Company would like to extend the term of your consultancy services for the period of 1 July 2022 to 30 June 2023.

- 1. Clause 8.1 (a) of the Agreement will be replaced with the following is replaced with the following:
"Subject to clause 8.1(b), Bionomics may terminate this agreement by paying severance of three (3) months of the fee set out in Schedule 3 of the agreement."
- 2. Clause 8.2 of the Agreement will be replaced with the following is replaced with the following:
"The Consultant may terminate this Agreement for any reason whatsoever by giving Bionomics three (3) month's written notice."
- 3. The first sentence in Schedule 2- Services of the Agreement will be replaced with the following sentence:
"The Consultant will devote approximately 100% of his time to perform the duties of Vice President of Strategy & Corporate Development."
- 4. Schedule 3 - Fees of the Agreement will be replaced with the following is replaced with the following:
"The fee shall for the provision of Executive Services shall be:
 - a) USD 22,500 per month or USD270,000 per year, payable by invoicing the Company at the end of each month during the provision of Executive Services.
 - b) Reimbursement for up to US\$10,000 in documented expenses for you for the purchase of Health Insurance or personal medical expenses.
 - c) Bonus target of 30% of USD 270,000 with 50% based on Company Goals and 50% based on Personal Goals

Please confirm your agreement to this amendment on the terms outlined in this letter by signing and dating this letter and returning it to me at your earliest convenience.

Yours sincerely
/s/ Errol de Souza
Errol B De Souza
Executive Chairman

/s/ Connor Bernstein
.....
Connor Bernstein

7/27/22
.....
Date

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Errol De Souza, Ph.D., certify that:

1. I have reviewed this Annual Report on Form 20-F of Bionomics Limited;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 14, 2022

By: /s/ Errol De Souza, Ph.D.
Errol De Souza, Ph.D.
Executive Chairman
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Adrian Hinton, certify that:

1. I have reviewed this Annual Report on Form 20-F of Bionomics Limited;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 14, 2022

By: /s/ Adrian Hinton
Adrian Hinton
Acting Chief Financial Officer
(Principal Finance Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

The certification set forth below is being submitted in connection with the Annual Report on Form 20-F for the year ended June 30, 2022 (the "Report") for the purpose of complying with Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code.

I, Adrian Hinton, certify that:

- (i) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Bionomics Limited.

Date: October 14, 2022

By: /s/ Adrian Hinton
Adrian Hinton
Acting Chief Financial Officer
(Principal Finance Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-261783) pertaining to the Employee Share Option Plan of Bionomics Limited, the Employee Equity Plan of Bionomics Limited, the Employee Equity Award Offer Letter with Errol De Souza, Ph.D. and the Employee Equity Award Offer Letter with Errol De Souza, Ph.D. of our report dated October 14, 2022, with respect to the consolidated financial statements of Bionomics Limited, included in this Annual Report on Form 20-F for the year ended June 30, 2022.

/s/ Ernst & Young

Adelaide, Australia
October 14, 2022

Exh. 15.1-1
