**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 December 31, 2023**

**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:

For the transition period from _____ to _____

**Commission file No. 001-37353**

**Scinai Immunotherapeutics Ltd.**
(Exact name of Registrant as specified in its charter)

**N/A**

(Translation of Registrant's name into English)

**ISRAEL**
(Jurisdiction of incorporation or organization)

**Jerusalem BioPark, 2nd floor**
**Hadassah Ein Kerem Campus**
**Jerusalem, Israel**
**(+972) 8-930-2529**
**(+972) 8-930-2531 (facsimile)**
(Address of principal executive offices)

**Amir Reichman,**
**Chief Executive Officer**
**(+972) 8-930-2529**
**(+972) 8-930-2531 (facsimile)**

(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 400 ordinary share, no par value** | **SCNI** | **Nasdaq Capital Market** |
| **Ordinary Shares, no par value*** | | |

* Not for trading on The Nasdaq Capital Market, but listed above only in connection with the registration of American Depositary Shares.

Securities registered or to be registered pursuant to Section 12(g) of the Act.

None
(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act.

None
(Title of Class)

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Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: 5,811,419 ordinary shares, no par value

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 ☒

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. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

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

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

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

Indicate by check mark 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. N/A

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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## INTRODUCTION

**Certain Definitions:**

In this annual report, unless the context otherwise requires:

- references to "Scinai," the "Company," "us," "we" and "our" refer to Scinai Immunotherapeutics Ltd. (the "Registrant"), an Israeli company;
- references to "ordinary shares," "our shares" and similar expressions refer to the Registrant's ordinary shares, no par value;
- references to "ADS" refer to the Registrant's American Depositary Shares
- references to "Company product candidate(s)" refer to any future, newly licensed or acquired product candidate(s);
- references to "CDMO business unit" refer to the Registrant's contract development and manufacturing services business unit.
- references to "R&D business unit" refer to the Registrant's research and development business unit focused on in-house development of inflammation and immunology (I&I) biological therapeutic products beginning with an innovative, de-risked, pipeline of nanosized VHH antibodies (NanoAbs) targeting diseases with large unmet medical needs.
- references to "dollars," "U.S. dollars" and "$" are to United States Dollars;
- references to "shekels" and "NIS" are to New Israeli Shekels, the Israeli currency;
- references to the "Companies Law" are to Israel's Companies Law, 5759-1999, as amended; and
- references to the "SEC" are to the United States Securities and Exchange Commission.

**Trademarks and Tradenames**

Solely for convenience, the trademarks, service marks and trade names referred to or incorporated by reference herein 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 herein are, to our knowledge, the property of their respective owners. Nanobody is a trademark registered by ABLYNX N.V., a wholly owned subsidiary of Sanofi. Scinai has no affiliation with and is not endorsed by Sanofi. We do not intend our use or display of other companies' trademarks, service marks or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

**Note Regarding Forward-Looking Statements**

Some of the statements under the sections entitled "Item 3. Key Information – Risk Factors," "Item 4. Information on the Company," and "Item 5. Operating and Financial Review and Prospects" and elsewhere in this Annual Report on Form 20-F constitute forward-looking statements that are subject to risks and uncertainties. These forward-looking statements include information about possible or assumed future results of our business, financial condition, results of operations, liquidity, plans and objectives. In some cases, you can identify forward-looking statements by terminology such as "believe," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "potential," or the negative of these terms or other similar expressions, but these are not the only ways these statements are identified. Forward-looking statements are based on information we have when those statements are made or our management's good faith belief as of that time with respect to future events and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Unless we are required to do so under U.S. federal securities laws or other applicable laws, we do not intend to update or revise any forward-looking statements.

Some of the factors that could cause our actual results to differ materially from those expressed or implied in the forward-looking statements contained herein, include but are not limited to:

- We are a developmental stage biopharmaceutical company with a history of operating losses, with no product candidate that generates revenue and as such we are not currently profitable, do not expect to become profitable in the near future, may never become profitable and as a result may need to wind up our business and operation;
- We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts;
- Our failure to meet the continued listing requirements of The Nasdaq Stock Market LLC ("Nasdaq") could result in a delisting of the ADSs which could adversely affect the market liquidity of our shares and the market price of our shares could decrease significantly;
- Our business strategy may not be successful;
- If we breach certain provisions of our 24 million Euro finance agreement with the the European Investment Bank (the "EIB") it could result in the EIB accelerating the loans thereunder and exercising secured creditor remedies over collateral securing those loans, and that collateral consists of substantially all of our assets. The exercise of such remedies may have a material adverse effect on our company. We do not have control over certain events that constitute a breach of this finance documentation;
- We conduct most of our operations in Israel. Conditions in Israel, including the recent attack by Hamas and other terrorist organizations from the Gaza Strip and Israel's war against them, may affect our operations.
- We are highly dependent upon our ability to enter into agreements with partners to develop, commercialize, and market any current and future product candidate(s) or enter into other strategic partnerships;
- Raising additional capital may cause dilution to our existing shareholders, and debt financing, if available, may restrict our operations or require us to relinquish rights to our technologies or product candidate(s);
- Our novel nanosized antibodies, also known as VHH-antibodies, Nanobodies or NanoAbs, represent a relatively new approach to treating diseases, and we must

**Commented [GGS2]:** List below from recent F-3 filing with revisions

**Commented [AR3R2]:** @Perry Wildes is that supposed to be a comprehensive list of all the RFs? Because it doesn't cover all the RFs I think

**Commented [SB4R2]:** the list is supposed to include some of the factors which may cause the company's results to differ materially from those in the forward-looking statements

overcome significant challenges in order to successfully develop, commercialize and manufacture product candidates based on this technology;

- Clinical trials are very expensive, time-consuming and difficult to design and implement, and, as a result, we may suffer delays or suspensions in future trials which would have a material adverse effect on our ability to generate revenues;

- Positive results from earlier preclinical data and clinical trials we conduct may not be predictive of the results in later clinical trials of current and future product candidates, and the results of any clinical trials we conduct may not be replicated in additional clinical trials that we may be required to conduct, which could result in development delays or a failure to obtain marketing approval;

- We may be unsuccessful in adapting our COVID-19 NanoAbs to protect against future variants of COVID-19. Furthermore, any commercialization of our COVID-19 NanoAbs may be adversely affected to the extent that the coronavirus disease evolves worldwide. We have suspended further development of this program due to changing market conditions for COVID therapeutics and may not continue unless we find a partner to further develop this program;

- We may not be successful in finding a partner to further develop our COVID-19 NanoAbs program. Such partners may be commercial, pharmaceutical companies or governmental agencies. As we have currently suspended our own development of this program, we are reliant on finding a partner to take the COVID-19 NanoAbs program to clinical trials;

- If we are not successful in discovering, developing and commercializing current and future product candidates, our ability to expand our business and achieve our strategic objectives may be impaired;

- Under the collaboration agreement with Max Planck Society, or MPG, and the University Medical Center Göttingen, or UMG, we have the option to in-license up to 9 total NanoAbs. To date, we have licensed anti-COVID-19 NanoAbs and anti-IL-17 NanoAbs. The anti-IL-17 NanoAbs are potential candidates to treat psoriasis and other conditions where over expression of IL-17 is implicated in creating or exacerbating the disease. There are many competitors targeting IL-17, including a significant number with far greater resources and/or further advanced in clinical development. We may be unsuccessful in in-licensing additional NanoAbs from MPG and UMG, or developing, and/or commercializing any of our NanoAbs;

- We are a developmental stage biopharmaceutical company with no product candidate(s) in clinical development or approved, which makes it difficult to assess our future viability;

- We face significant competition. If we cannot successfully compete with new or existing product candidate(s), our marketing and sales will suffer, and we may never be profitable;

- Our NanoAbs program is based on an exclusive license fromMPG and UMG, and we could lose our rights to this license if a dispute with MPG and/or UMG arises or if we fail to comply with the financial and other terms of the license;

- We recently announced our plans to utilize our manufacturing site and laboratories by launching a CDMO Business Unit. There is no guarantee that our strategy will succeed, that we will be able to ramp up operations, or that we will become profitable;

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- CDMO services are highly complex and failure to provide quality and timely services to our CDMO clients, could adversely impact our business;

- Significant delays in product manufacturing or development and in our ability to produce sufficient quantities to meet the needs of our clients could cause delays in recognizing revenues, which would harm our business, financial condition, operating results and cash flows.

A disruption to our GMP biologics manufacturing facility in Jerusalem could impede our ability to advance our NanoAbs programs and deliver our CDMO services, which could adversely affect our business

## 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

*An investment in our securities involves a high degree of risk. Before making an investment decision, you should carefully consider the factors described below, together with all other information included in this annual report, including our financial statements and the related notes included elsewhere in this annual report. We may face additional risks and uncertainties not currently known to us or that we currently deem to be immaterial. If any of these risks occur, our business, financial condition, results of operations and business prospects could be materially and adversely affected. In that event, the trading price of the ADSs could decline and you could lose all or part of your investment.*

**Summary of Risk Factors** The following is a summary of some of the principal risks we face. The list below is not exhaustive, and investors should read this "Risk factors" section in full.

- We are a developmental stage biopharmaceutical company with a history of operating losses, with no product candidate that generates revenue and as such we are not currently profitable, do not expect to become profitable in the near future, may never become profitable and as a result may need to wind up our business and operation.

- We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

- Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of the ADSs which could adversely affect the market liquidity of our shares and the market price of our shares could decrease significantly

- Our business strategy may not be successful.

- If we breach certain provisions of our 24 million Euro finance documentation with the EIB it could result in the EIB accelerating the loans thereunder and exercising secured creditor remedies over collateral securing those loans, and that collateral consists of substantially all of our assets. The exercise of such remedies may have a material adverse effect on our company. We do not have control over certain events that constitute a breach of this finance documentation.

- We are highly dependent upon our ability to enter into agreements with partners to develop, commercialize, and market any current and future product candidate(s) or enter into other strategic partnerships.

- Raising additional capital may cause dilution to our existing shareholders, and debt financing, if available, may restrict our operations or require us to relinquish rights to our technologies or product candidate(s);

- Our novel nanosized antibodies, also known as VHH-antibodies, Nanobodies or NanoAbs, represent a relatively new approach to treating diseases, and we must overcome significant challenges in order to successfully develop, commercialize and manufacture product candidates based on this technology.

- Clinical trials are very expensive, time-consuming and difficult to design and implement, and, as a result, we may suffer delays or suspensions in future trials which would have a material adverse effect on our ability to generate revenues.

- Positive results from earlier preclinical data and clinical trials we conduct may not be predictive of the results in later clinical trials of current and future product candidates, and the results of any clinical trials we conduct may not be replicated in additional clinical trials that we may be required to conduct, which could result in development delays or a failure to obtain marketing approval.

- We may be unsuccessful in adapting our COVID-19 NanoAbs to protect against further variants of COVID-19 and in finding a partner to further develop our COVID-19 NanoAb. Furthermore, any commercialization of our COVID-19 NanoAbs may be adversely affected to the extent that the coronavirus disease evolves worldwide.

- If we are not successful in discovering, developing and commercializing current and future product candidates, our ability to expand our business and achieve our strategic objectives may be impaired.

- We are a developmental stage biopharmaceutical company with no product candidate(s) in clinical development or approved, which makes it difficult to assess our future viability.

- We face significant competition. If we cannot successfully compete with new or existing product candidate(s), our marketing and sales will suffer, and we may never be profitable.

- Our NanoAbs program is based on an exclusive, worldwide license from the Max Planck Society, and we could lose our rights to this license if a dispute with MPG arises or if we fail to comply with the financial and other terms of the license.

- CDMO services are highly complex and failure to provide quality and timely services to our CDMO clients, could adversely impact our business.

- Significant delays in product manufacturing or development and our ability to produce sufficient quantities to meet the needs of our clients could cause delays in recognizing revenues, which would harm our business, financial condition, operating results and cash flows.

- A disruption to our GMP biologics manufacturing facility in Jerusalem could impede our ability to advance our NanoAbs programs and deliver our CDMO services, which could adversely affect our business.

**Risks Related to Our Financial Position and Capital Requirements**

***Our financial statements include a going concern reference. We will need to raise significant additional capital to finance our losses and negative cash flows from operations, and if we were to fail to do so, or if the European Investment Bank, or EIB, accelerate their loans to us under our finance contract with EIB, we may need to cease operations. Management has substantial doubt about our ability to continue as a going concern.***

As of December 31, 2023, the Company's cash and cash equivalents totaled $4.9 million. In the twelve months ended December 31, 2023, the Company had an operating loss of $9.7 million and negative cash flows from operating activities of $9.3 million. The Company's current cash and cash equivalents position is not sufficient to fund the Company's planned operations for at least a year beyond the date of the filing date of the financial statements. Those factors raise substantial doubt about the Company's ability to continue as a going concern. The ability to continue as a going concern is dependent upon the Company obtaining the necessary financing to meet its obligations and repay its liabilities arising from normal business operations when they become due. While the Company has successfully raised funds in the past, there is no guarantee that it will be able to do so in the future. The inability to borrow or raise sufficient funds on commercially reasonable terms, would have serious consequences on our financial condition and results of operations.

In addition, we borrowed 24 million Euro under a finance contract with EIB (the "Finance Contract") with a maturity date of December 31, 2031. Under the Finance Contract, the EIB may accelerate all loans extended thereunder if an event of default has occurred. If the EIB determines that an event of default has occurred, it could accelerate the amounts outstanding under the Finance Contract, making those amounts immediately due and payable. In such a case, we expect such events to adversely impact our ability to continue as a going concern.

The Company's current operating budget includes various assumptions concerning the level and timing of cash receipts and cash outlays for operating expenses and capital expenditures, including a cost saving plan. The Company is planning to finance its operations from its existing working capital resources and additional sources of capital and financing that are in the advanced planning phase. However, there is no assurance that additional capital and/or financing will be available to the Company, and even if available, whether it will be on terms acceptable to the Company or in amounts required, particularly if we are not able to maintain our listing on Nasdaq. See "- Risks Related to our Securities - Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of the ADSs. The delisting could adversely affect the market liquidity of our shares and the market price of our shares could decrease significantly." Accordingly, the Company's board of directors approved a cost saving plan, a portion of which has been implemented to date. Additional measures approved in the cost reduction plan could further be implemented at management discretion to allow the Company to continue its operations and meet its cash obligations. The cost saving plan consists of reducing expenditures by means of further efficiencies and synergies, which include mainly the following steps: reduction in headcount costs through nonpaid leave and lay-offs, and postponing and/or cancelling capital expenditures that would not be required for the implementation of the revised business plan.

The Company's financial statements for the twelve-months ended December 31, 2023 were prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and liabilities and commitments in the normal course of business. Such financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

From F-1/A **:Commented [SB5]**

**Commented [GGS6R5]:** Moved here from lower down due to its materiality

**Commented [MG7R5]:** assuming we get a letter from the EIB stating it is open to converting the debt to equity, this section needs to be revised to contemplate that, subject to finalization of such a restructuring.

***We are a developmental stage biopharmaceutical company with a history of operating losses, with no product candidate that generates revenue and as such we are not currently profitable, do not expect to become profitable in the near future, may never become profitable and as a result may ultimately need to wind up our business and operation.***

We are a development stage biopharmaceutical company and currently do not have, and may never have, any product candidate(s) that generate revenues. Our CDMO Unit has generated limited revenues to date. Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate(s) will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable.

We are not profitable and have incurred losses since inception, principally as a result of research and development, clinical trials, construction of our GMP biologics manufacturing facility, and general administrative expenses in support of our operations. We have not generated any revenue, expect to incur substantial losses for the foreseeable future and may never become profitable. As of December 31, 2023, we had an accumulated deficit of $122.5 million, and we expect to experience negative cash flow for the foreseeable future. As a result, we will ultimately need to generate significant revenues in order to achieve and maintain profitability. We may never be able to generate revenues or achieve profitability in the future, and we expect to incur additional losses for the foreseeable future. Our failure to achieve or maintain profitability, or substantial delays in achieving profitability, could negatively impact the value of the securities and our ability to raise additional financing. A substantial decline in the value of the securities would also affect the price at which we could sell them to secure future funding, which could dilute the ownership interest of current shareholders. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Accordingly, it is difficult to evaluate our business prospects. Moreover, our prospects must be considered in light of the risks and uncertainties encountered by an early-stage company in highly regulated and competitive markets, such as the biopharmaceutical market, where regulatory approval and market acceptance of our product candidate(s) are uncertain. There can be no assurance that our efforts will ultimately be successful or result in revenues or profits.

***We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.***

As of December 31, 2023, we had $4.9 million in cash and cash equivalents and short-term deposits, working capital of $3.6 million and an accumulated deficit of $122.3 million. Our existing cash resources are not sufficient to fund our projected cash requirements at current monthly rates for at least the next 12 months.

Our ability to execute on our business plan is dependent upon our ability to raise capital through private or public financings, or enter into a commercial agreement, among others. Since our inception, most of our resources have been dedicated to product development. In the future, we believe that we will expend significant operating and capital expenditures to acquire additional product candidates, develop and, subject to results of any future clinical trials, apply for regulatory approval of current and future product candidates, if any. These expenditures may include, but are not limited to, costs associated with research and development, manufacturing, conducting clinical trials, contract manufacturing organizations, or CMOs, hiring additional management and other personnel, applying for regulatory approvals, acquisition of equipment, as well as commercializing any product candidates approved for sale. Furthermore, we incur additional costs associated with operating as a public company traded on Nasdaq in the United States. We cannot precisely estimate the actual amounts necessary to acquire additional product candidates and successfully complete the development and commercialization of product candidates. As a result of these and other factors currently unknown to us, we will require additional funds, through public or private equity or debt financings or non-dilutive sources or other sources, that may not be available to us or, if available, may not be on terms favorable to us. A failure to fund these activities may significantly harm our growth strategy, competitive position, quality compliance, financial condition and is expected to have a material adverse effect on our business and operations.

Our future capital requirements depend on many factors, including:

- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- our search for new business opportunities;
- our ability to identify and acquire rights to, or develop on our own, new product candidate(s) and diversify/expand our product opportunities;
- the scope and cost of researching and developing, obtaining regulatory approval for, commercializing and manufacturing any new product candidate(s);
- our ability to generate significant revenue from our CDMO business unit.
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the expenses needed to attract and retain skilled personnel; and
- any product liability or other lawsuits related to any current or future product candidate(s).

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate the potential acquisition of other product candidates, preclinical studies, clinical trials or other research and development activities for current and future product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize such product candidate(s).

***Our business strategy may not be successful.***

We cannot offer any assurance that our business strategy will be successful. If we are unable to successfully execute our business strategy, our business, financial condition and results of operations may be materially and adversely affected.

***Raising additional capital may cause dilution to our existing shareholders, and debt financing, if available, while an inability to raise additional capital may restrict our operations or require us to relinquish rights to our technologies or product candidate(s).***

We may seek additional capital through a combination of private and public equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing shareholders will be diluted, and the terms may include liquidation or other preferences that adversely affect shareholder rights. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring future indebtedness, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships, alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or any product candidate(s) or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate any product development or commercialization efforts, or grant rights to develop and market product candidate(s) that we would otherwise prefer to develop and market ourselves.

***If we breach certain provisions of our 24 million Euro finance documentation with the EIB, the EIB could accelerate the loans thereunder and exercise secured creditor remedies over collateral securing those loans, and that collateral consists of substantially all of our assets. The exercise of such remedies may have a material adverse effect on our company. We do not have control over certain events that constitute a breach of this finance documentation.***

We borrowed 24 million Euro under a finance contract (the "Finance Contract") with the EIB, to finance a portion of the cost of developing our previous leading drug candidate M-001 (Universal

Influenza Vaccine drug candidate) and our GMP biologics manufacturing facility. The Finance Contract was amended on August 10, 2022 to extend the maturity of the loan until December 2027 and adding and amending certain additional terms (see "Finance Contract with the European Investment Bank" above), and amended again in November 2023 to further extend the maturity until December 2031.

**Commented [MG8]:** see above comment re possible conversion of EIB debt into equity

As part of the Finance Contract, we also entered into a security agreement (the "Security Agreement"), whereby we created a first ranking floating charge in favor of EIB over substantially all of our assets (other than certain licensed intellectual property related to our former M-001 program). While intellectual property rights are excluded from the floating charge pledge, certain breaches of the Finance Contract or the Security Agreement may cause the EIB to exercise secured creditor remedies under the floating charge pledge and foreclose on certain of our assets at the time of such exercise.

Under the Finance Contract we are not allowed to make any senior management changes without the consent of the EIB. We will be required to obtain consents from the EIB in the future if any senior management change is expected to occur and in such an event, the EIB's consent is not guaranteed. In addition, we may not be able to anticipate a future change to our senior management and in such an event, we may not be able to obtain the consent of the EIB ahead of such an event. If we are not able to receive the EIB's consent before such change in our senior management or we decide to change our senior management without first obtaining the consent of the EIB, which we may be forced to do or may elect to do in order to address business concerns, the EIB may accelerate all loans extended to us under the Finance Contract, and exercise secured creditor remedies against the collateral securing those loans. In such an event we may not be able to continue our business and operations as a going concern.

Furthermore, under the Finance Contract, the EIB may accelerate all loans extended thereunder if an event of default has occurred, which includes, amongst other things, an event of default arising from the occurrence of a material adverse change, defined as any event or change of condition, which in the opinion of the EIB, has a material adverse effect on: our ability to perform our obligations under the Finance Documents; our business, operations, property, condition (financial or otherwise) or prospects; or the rights or remedies of the EIB under the Finance Contract, amongst other things. If the EIB determines that an event of default has occurred, it could accelerate the amounts outstanding under the Finance Contract, making those amounts immediately due and payable.

If an event of default occurs under the Finance Contract, all loans extended under the Finance Contract can be accelerated and secured creditor remedies may be exercised. If some or all of the loans under the Finance Contract are accelerated by the EIB, or secured creditor remedies are exercised, we expect such events to adversely impact our ability to continue as a going concern.

**Risks Related to Development, Clinical Testing and Regulatory Approval of NanoAbs and Any Other Current and Future Product Candidate(s)**

***We have not yet commercialized any product candidate(s), and we may never become profitable.***

We are party to a licensing and collaboration arrangement with MPG and University Medical Center Göttingen. pursuant to which we are working to develop and commercialize a pipeline of innovative NanoAb drugs addressing diseases with large underserved medical needs and attractive commercial opportunities. Our first program was development of an inhalable COVID-19 NanoAb, and while we were able to demonstrate positive results in an industry accepted hamster model of COVID-19, the market for COVID-19 therapeutics has decreased significantly, and with it capital sources. Accordingly, due to changing market conditions for COVID therapeutics we have suspended further development of the COVID-19 NanoAb and are now focused on the development of VHH antibodies (NanoAbs) targeting Interleukin-17 (IL-17) as treatments for all potential indications where IL-17 plays a meaningful role, starting with psoriasis and psoriatic arthritis. . Aside from this, we have no product candidates in pre-clinical development, in clinical trials or on the market. Even if we are successful in developing current or future product candidates, we will not be successful unless we complete our product development efforts, obtain regulatory approval and such product candidate(s) gain(s) market acceptance for appropriate indications at favorable reimbursement rates. The degree of market acceptance of these product candidate(s) will depend on a number of factors, including, but not limited to:

- the timing of regulatory approvals in the U.S. and other countries, if any, and the uses for which we intend to pursue regulatory approval for the commercialization of current and future product candidates
- the competitive environment;
- the demand for our product candidate(s);
- the establishment and demonstration in, and acceptance by, the medical community of the safety and clinical efficacy of our product candidate(s) and its potential advantages over other competitive products;
- our ability to enter into supply agreements with health organizations and governments around the world for the supply of our product candidate(s) or our ability to enter into strategic agreements with pharmaceutical and biopharmaceutical companies with strong marketing and sales capabilities;
- the adequacy and success of our distribution, sales and marketing efforts; and
- the pricing, coverage and reimbursement policies of government and third-party payors, such as insurance companies, health maintenance organizations and other plan administrators.

Physicians, participants, third-party payors or the medical community in general may be unwilling to accept, utilize or recommend, and in the case of third-party payors, cover payment for current and future product candidates. As a result, we are unable to predict the extent of our future losses or the time required for us to achieve profitability, if at all. Even if we successfully develop one or more products, we may not become profitable.

In addition, we have limited marketing capabilities, and if we are unable to enter into collaborations with marketing partners or develop our own sales and marketing capabilities, we may not be successful in commercializing current and future product candidates. If we are unable to reach and maintain agreements with one or more pharmaceutical companies or partners, we may be required to market our product candidate(s) directly. Developing a marketing and sales force is expensive and time-consuming and could delay a product launch. We may not be able to attract and retain qualified sales personnel or otherwise develop this capability.

***NanoAbs represent a relatively new approach to treating diseases, and we must overcome significant challenges in order to successfully develop, commercialize and manufacture product candidates based on this technology.***

We are currently concentrating our development efforts on the IL-17 NanoAb as a treatment for all potential indications where IL-17 plays a meaningful role, starting with psoriasis and psoriatic arthritis. The processes and requirements imposed by the U.S. Food and Drug Administration (the "FDA") or other applicable health authorities may cause delays and additional costs in obtaining approvals for marketing authorization for our products. Because our platform is relatively new and only one drug developed by a competing company and related to rare blood diseases has been approved to date in the market, regulatory agencies, as well as insurance and other coverage providers and payers, may lack experience in evaluating our product candidates. This inexperience may lengthen the regulatory review process, increase our development costs and delay or prevent reimbursement and commercialization of our platform products. Additionally, advancing this novel platform creates significant challenges for us, and we must be able to overcome these challenges in order to successfully develop, commercialize and manufacture our product candidates.

***In light of our current resources and limited commercial experience, we have and may need to continue to establish third-party relationships to successfully develop, commercialize and market our pipeline candidates.***

Our long-term commercial viability may depend, in part, on our ability to successfully execute current strategic collaborations and establish new strategic collaborations with contract commercial

organizations, pharmaceutical and biotechnology companies, non-profit organizations, and government agencies. Establishing and maintaining strategic collaborations and obtaining government funding is difficult and time-consuming. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position or based on their internal pipeline or available resources; government agencies may reject contract or grant applications based on their assessment of public need, the public interest, the ability of our products to address these areas, or other reasons beyond our expectations or control. If we fail to establish or maintain collaborations necessary for successful development, commercialization and marketing on acceptable terms, we may not be able to develop, commercialize or market product candidates or generate sufficient revenue to fund further research and development efforts.

New or existing collaborations, including our collaboration with MPG and UMG, may never result in the successful development or commercialization of any pipeline candidates for several reasons, including the fact that:

- we may not have the ability to control the activities of our partners and cannot provide assurance that they will fulfill their obligations to us, including with respect to the license, development, and commercialization of pipeline candidates, in a timely manner or at all;
- such partners may not devote sufficient resources to our pipeline candidates or properly maintain or defend our intellectual property rights (if required)
- such partners may decide to pursue competitive product candidates developed outside of the partnership arrangement;
- any failure on the part of our partners to perform or satisfy their obligations to us could lead to delays in the development or commercialization of our pipeline candidates and affect our ability to realize product revenue;
- disagreements, including disputes over the ownership of technology developed with such collaborators, could result in litigation, which would be time-consuming and expensive, and may delay or terminate research and development efforts, regulatory approvals, and commercialization activities; and
- such partners may decide to terminate or not to renew the collaboration for these or other reasons.

If we or our collaborators fail to maintain our existing agreements or in the event we fail to establish agreements as necessary, we could be required to undertake research, development, manufacturing, and commercialization activities solely at our own expense. These activities would significantly increase our capital requirements and, given our lack of sales, marketing and distribution capabilities, significantly delay the commercialization of our pipeline candidates.

***Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required, and we may not adequately develop such protocols to support approval.***

In addition to FDA requirements and those of other regulatory authorities, an independent institutional review board or an independent ethics committee at each medical institution proposing to participate in the conduct of the clinical trial generally must review and approve the clinical trial design and patient informed consent form before commencement of the study at the respective medical institution. The institutional review boards approve the clinical trial protocols and conduct periodic reviews of the clinical trials. The clinical trial protocols describe the type of people who may participate in the clinical trial, the schedule of tests and procedures, the medications and dosages to be studied, the length of the study, the study's objectives, and other details. In general, the institutional review board will consider, among other matters, ethical factors, the safety of human subjects and the possibility of liability of the institution conducting the trial. Our pre-clinical studies may not be adequate proof of safety and efficacy, and as a result, we may not be successful in developing clinical trial protocols necessary to support institutional review board approval. Any delay or failure to obtain institutional review board approval to conduct a clinical trial at a prospective site could materially impact the costs, timing, or successful completion of a clinical trial.

***Current and future product candidates would be subject to extensive regulation and may never obtain regulatory approval.***

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidate(s) are subject to extensive regulation by the Food and Drug Administration (the "FDA") in the United States (the "U.S.") as detailed in Title 21 of the U.S. Code or elsewhere and by comparable authorities in foreign markets. In the U.S., we are not permitted to market our product candidate(s) until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the product candidate(s) involved, as well as the target indications and patient population. Current and future product candidates must satisfy rigorous standards of safety and efficacy before product candidates can be approved for commercial use by the European Medicines Agency (the "EMA") in the European Union (the "EU") or the FDA in the U.S., or any other regulatory authorities for all or any of the indications for which product candidates are intended to be used. The EMA, FDA and any other regulatory authorities have substantial discretion over the approval process, and approval is never guaranteed. We may need to conduct significant additional research before we can file applications for product approval. Typically, in the pharmaceutical industry, there is a high rate of attrition for product candidates in clinical trials. Success in early clinical trials does not ensure that later clinical trials will be successful. For example, a number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate(s) for many reasons, including:

- such authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or other comparable regulatory authorities in foreign markets that a product candidate(s) is safe and effective for any indication;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the U.S.;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- approval may be granted only for indications that are significantly more limited than what we apply for and/or with other significant restrictions on distribution and use; or
- such authorities may find deficiencies in manufacturing processes or facilities, including the processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies.

In addition, delays or rejections may be encountered based upon additional government regulation, including any changes in legislation or policy of the EMA, FDA or any other regulatory policy, during the process of product development, clinical trials and regulatory reviews. Approval procedures vary among countries, and may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the EMA, FDA and comparable foreign regulatory authorities in reviewing new pharmaceutical products based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Failure to obtain EMA, FDA or any other regulatory approval for current and future product candidates in a timely manner or at all will severely undermine our business by delaying or halting

commercialization of our products, imposing costly procedures, diminishing competitive advantages and reducing the number of saleable products and, therefore, corresponding product revenues.

***Current and future product candidates will remain subject to ongoing regulatory requirements even if we receive regulatory approval to market such product candidate(s), and if we fail to comply with such requirements, we could lose those approvals that have been obtained, and the sales of any approved commercial products could be suspended.***

Even if we receive regulatory approval to market current and future product candidates, such product candidate(s) will remain subject to extensive regulatory requirements, including requirements relating to manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and record keeping. Even if regulatory approval of any product candidate(s) is granted, approval may be subject to limitations on the uses for which the product candidate(s) may be marketed or the conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product candidate(s), which could negatively impact us or our collaboration partners by reducing revenues or increasing expenses, and cause the approved product candidate(s) not to be commercially viable. In addition, as clinical experience with a drug expands after approval, typically because it is used by a greater number and more diverse group of people after approval than during clinical trials, side effects and other problems may be observed over time after approval that were not seen or anticipated during pre-approval clinical trials or other studies. Any adverse effects observed after the approval and marketing of a product candidate(s) could result in limitations on the use of, withdrawal of EMA, FDA or any other regulatory approval or withdrawal of any approved product candidate(s) from the marketplace. Absence of long-term safety data may also limit the approved uses of our product candidate(s), if any. If we fail to comply with the regulatory requirements of the EMA, FDA and any other applicable regulatory authorities, or previously unknown problems with any approved commercial product candidate(s), manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions or other setbacks, including, without limitation, the following:

- suspension or imposition of restrictions on the product candidate(s), manufacturers or manufacturing processes, including costly new manufacturing requirements;
- warning letters;
- civil or criminal penalties, fines and/or injunctions;
- product seizures or detentions;
- import or export bans or restrictions;
- voluntary or mandatory product recalls and related publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production; and
- refusal to approve pending applications for marketing approval of new product candidate(s) or supplements to approved applications.

If we or our partners, if any, are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements or policies, marketing approval for our product candidate(s) may be lost or cease to be achievable, resulting in decreased revenue from milestones, product sales or royalties, or otherwise, which would have a material adverse effect on our business, financial condition or results of operations.

***Current and future product candidates, if approved, may face competition sooner than anticipated.***

Our product candidates may face serious competition from other products targeting the same disease or condition, including biosimilar products. In the U.S., current and future product candidates may be regulated by the FDA as biologic products and we may seek approval for such product

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candidate(s) pursuant to the biologics license application, or BLA, pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, amended the Public Health Service Act (the "PHSA") and created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until twelve years from the date on which the reference product was first licensed. During this twelve-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. This twelve-year period of exclusivity does not pre-empt and is independent of any patent protection afforded to current and future product candidates. The law is complex and is still being interpreted and implemented by the FDA. Any processes adopted by the FDA to implement the BPCIA could have a material adverse effect on the future commercial prospects for our biological products, if any.

Although we believe that current and future product candidates should qualify for the twelve-year period of exclusivity described above if product candidates are approved as biological products under a BLA, we may not be granted such exclusivity. Further, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider current and future product candidates to be reference products for competing products, potentially creating the opportunity for generic or biosimilar competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar product, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing. In addition, a competitor could decide to forego the biosimilar approval path and submit a full BLA after completing its own preclinical studies and clinical trials. In such cases, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its product as soon as it is approved.

***If the results of any future clinical trials show that current and future product candidates are effective based on certain endpoints but nevertheless fail to achieve all the primary/secondary endpoint(s) requiring us to conduct additional clinical trials, or if clinical trials that we conduct for such products in the future are prolonged or delayed, we would be unable to commercialize current and future product candidates on a timely basis, which would require us to incur additional costs and delay our receipt of any revenues from potential sales of such product candidate(s).***

If we fail to achieve all the primary/secondary endpoints, then we may be required by the FDA or any other regulatory authority to conduct additional clinical studies. We cannot predict whether we will encounter problems with any such clinical trials that will cause us or any regulatory authority to delay or suspend those clinical trials or delay the analysis of data derived from them. A number of events, including any of the following, could delay the completion of any such additional clinical trials and negatively impact our ability to obtain regulatory approval for, and to market and sell, a particular product candidate(s):

- conditions imposed on us by the FDA or any applicable foreign regulatory authority regarding the scope or design of our clinical trials;
- delays in recruiting and enrolling participants or volunteers into any potential future clinical trials;
- delays in obtaining, or our inability to obtain, required approvals from institutional review boards ("IRBs") or other reviewing entities at clinical sites selected for participation in our clinical trials;
- insufficient supply or deficient quality of our product candidate(s) or other materials necessary to conduct our clinical trials;
- lower than anticipated retention rate of subjects and participants in clinical trials;

- negative or inconclusive results from clinical trials, or results that are inconsistent with earlier results, that necessitate additional clinical studies;

- serious and unexpected drug-related side effects experienced by subjects and participants in clinical trials; or

- failure of our third-party contractors to comply with regulatory requirements or otherwise meet their contractual obligations to us in a timely manner.

Clinical trials require sufficient participant enrollment, which is a function of many factors, including the size of the participant population, the nature of the trial protocol, the proximity of participants to clinical sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial. Delays in participant enrollment can result in increased costs and longer development times. The failure to enroll participants in a clinical trial could delay the completion of the clinical trial beyond our current expectations. In addition, the FDA or foreign applicable regulatory authorities could require us to conduct clinical trials with a larger number of subjects than we have prior experience with. We may not be able to enroll a sufficient number of participants in a timely or cost-effective manner. Furthermore, enrolled participants may drop out of clinical trials, which could impair the validity or statistical significance of those clinical trials.

Prior to commencing clinical trials in the U.S., we must submit an Investigational New Drug ("IND") application to the FDA and the IND application must become effective.

Delays in any clinical trials the FDA or EMA may require us to conduct will result in increased development costs for current and future product candidates. In addition, if any such clinical trials are delayed, our competitors may be able to bring products to market before we do and the commercial viability of current and future product candidates could be limited.

***Clinical trials are very expensive, time-consuming and difficult to design and implement, and, as a result, we may suffer delays or suspensions in future trials which would have a material adverse effect on our ability to generate revenues.***

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Regulatory authorities, such as the EMA and FDA, may preclude clinical trials from proceeding. Additionally, the clinical trial process is time-consuming, failure can occur at any stage of the trials and we may encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- unforeseen safety issues;

- determination of proper dosing;

- lack of effectiveness or efficacy during clinical trials;

- failure of our contract manufacturers or inability of our in-house facility to manufacture our product candidate(s) in accordance with current good manufacturing practices, or cGMP;

- failure of third party suppliers to perform final manufacturing steps for the drug substance;

- slower than expected rates of participant recruitment and enrollment;

- lack of healthy volunteers and participants to conduct trials;

- inability to monitor participants adequately during or after treatment;

- Failure or delay in reaching an agreement with a third party contract research organization or clinical trial site(s), and failure of third party contract research organizations to properly implement or monitor the clinical trial protocols;

- failure of the FDA, Institutional Review Boards ("IRBs"), or other regulatory bodies to authorize our clinical trial protocols, or a decision by a regulatory body to place one or more of our trials on hold;

- inability or unwillingness of medical investigators and Contract Research Organizations to follow our clinical trial protocols and applicable regulatory requirements; and

- lack of sufficient funding to finance the clinical trials.

In addition, we or regulatory authorities may suspend or terminate our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks, if the regulatory authorities find deficiencies in our regulatory submissions or the conduct of these trials, if inspection of the clinical trial operations or trial site by a regulatory authority results in the imposition of a clinical hold, or if there is a failure to demonstrate a benefit from using the product candidate(s), or changes in governmental regulations or administrative actions. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Any suspension of clinical trials will delay possible regulatory approval, if any, and adversely impact our ability to develop product candidate(s) and generate revenue.

***We may in the future conduct clinical trials of current and future product candidates at sites outside the U.S., and the FDA may not accept data from trials conducted in foreign locations.***

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We may in the future conduct clinical trials of current and future product candidates outside of the U.S. Although the FDA may accept data from clinical trials conducted outside the U.S., acceptance of this data is subject to certain conditions imposed by the FDA. For example, under 21 Code of Federal Regulations ("CFR") 312.20, the clinical trial must be well designed and conducted in accordance with good clinical practice, or GCP, requirements, and the FDA must be able to validate the clinical trial data through an on-site inspection, if necessary, among other things. If a marketing application is based solely on foreign clinical data, the FDA can require such data to be applicable to the U.S. population and U.S. medical practice, and for the clinical trials to have been performed by clinical investigators of recognized competence. There can be no assurance the FDA will accept data from trials conducted outside of the U.S. If the FDA does not accept the data from any clinical trials that may be conducted outside of the U.S. of current and future product candidates, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of the product candidate(s).

***Positive results from earlier preclinical data and clinical trials may not be predictive of the results in later clinical trials of current and future product candidates, and the results of our clinical trials may not be replicated in additional clinical trials that we may be required to conduct, which could result in development delays or a failure to obtain marketing approval.***

Positive results from previous clinical trials may not be predictive of the results of later clinical trials of current and future product candidates, and any early clinical trials may not be predictive of results in later clinical trials that we may conduct. A number of companies in the pharmaceutical and biopharmaceutical industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from preclinical studies and clinical trials for current and future product candidates may not be predictive of the results we may obtain in later stage trials.

For example, the COVID-19 NanoAbs licensed by us from UMG and MPG have demonstrated strong neutralization at very low concentrations of major Variants of Concern ("VoCs") of COVID-19 (including Alpha, Beta, Gamma, Delta, and Omicron) in in-vitro studies, and for Wuhan also in a preclinical in vivo trial. These studies are not a guarantee of success in future preclinical or clinical trials, nor can the Company guarantee that the NanoAbs will neutralize any potential future VoCs, nor can the Company guarantee that the Company together with their partners at MPG and UMG will successfully isolate new NanoAbs against any newly emerging VoCs. Furthermore, even if preclinical studies are able to demonstrate the potential safety and efficacy of our product candidates, there can be no guarantee that such results will be reproducible in clinical trials involving human subjects.

Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain FDA or European Medicines Agency, or other applicable regulatory agency, approval for their product candidates.

***We may be unsuccessful in adapting our COVID-19 NanoAbs to protect against future variants of COVID-19 and in finding a partner to further develop our COVID-19 NanoAbs. Furthermore, any commercialization of our COVID-19 NanoAbs may be adversely affected to the extent that the coronavirus disease evolves worldwide.***

The SARS-CoV-2 virus continues to evolve, and new strains of the virus or those that are already in circulation may prove more transmissible or cause more severe forms of COVID-19 disease than the predominant strains to date. There is a risk that our COVID-19 NanoAbs will not be effective in protecting against emerging and circulating variant strains of the SARS-CoV-2 virus, or that we will develop COVID-19 NanoAbs for a variant that will not have a sufficient number of participants for a clinical trial.

Furthermore, there are a number of preventative vaccines in development and others that have already been approved and widely distributed. If the COVID-19 pandemic subsides or the COVID-19 disease does not evolve into a seasonally recurrent disease, it may reduce demand for our COVID-19 NanoAbs.

We have suspended further development of the COVID-19 NanoAbs program due to changing market conditions for COVID therapeutics and may not continue unless we find a partner to further develop this program. Such partners may be commercial, pharmaceutical companies or governmental agencies. We may not be successful in finding a partner to further develop our COVID-19 NanoAbs, and even if we are successful, there is no guarantee that the partner will be successful in developing our COVID-19 NanoAbs or that there will be sufficient market demand for COVID-19 NanoAbs. See also " – In light of our current resources and limited commercial experience, we have and may need to continue to establish third-party relationships to successfully commercialize our pipeline candidates."

***We have limited experience with the development of local delivery and inhalation-administered therapies.***

We intend to develop our anti-IL-17 NanoAbs to be administered by local delivery. If the development of our COVID-19 NanoAb is continued, we expect that it would be developed to be administered by inhalation, targeting the virus directly in the lungs and airways. Although our team has significant experience with designing and conducting clinical trials, we have never developed or commercialized a local delivery therapy or an inhalation-administered therapy. Even if our anti-IL-17 NanoAbs are effective against potential indications where IL-17 plays a meaningful or our COVID-19 NanoAbs are effective against COVID-19, we are subject to development risks associated with these routes of administration.

***If we experience delays in the enrollment of participants in any future clinical trials we may conduct, our receipt of necessary regulatory approvals could be delayed or prevented.***

We may not be able to initiate clinical trials for current and future product candidates. Participant enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the population eligible to participate, the proximity of potential participants to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and participants' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. If we fail to enroll and maintain the number of participants for which the clinical trial was designed, the statistical power of that clinical trial may be reduced, which would make it harder to demonstrate that the product candidate being tested in such clinical trial is safe and effective. Additionally, enrollment delays in any clinical trials may result in increased development costs for current and future product candidates, which could materially harm our financial condition and limit

our ability to obtain additional financing. Our inability to enroll a sufficient number of participants for any clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

***The occurrence of serious complications or side effects in connection with current and future product candidates, either in future clinical trials we may conduct or post-approval, could impede such future clinical trials, if any, and lead to refusal of regulatory authorities to approve our product candidate(s) or, post-approval, revocation of marketing authorizations or refusal to approve new indications, which could severely harm our business, prospects, operating results and financial condition.***

In any future clinical trials of current and future product candidates that we may conduct, or following regulatory approval, illnesses, injuries, discomforts and other adverse events may be reported by subjects. In addition, side effects are sometimes only detectable after they are made available to patients on a commercial scale after approval. Results of any future clinical trials we may undertake for current and future product candidates could reveal a high and unacceptable severity and prevalence of such side effects. In such an event, any clinical trials we may conduct 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 current and future product candidates for any or all targeted indications. Drug-related side effects could affect patient recruitment for any clinical trials we may conduct or the ability of enrolled participants to complete such trials or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

- such authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or other comparable regulatory authorities in foreign markets that a product candidate(s) is safe and effective for any indication;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the U.S.;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- approval may be granted only for indications that are significantly more limited than what we apply for and/or with other significant restrictions on distribution and use; or
- such authorities may find deficiencies in manufacturing processes or facilities.

Any of these events could prevent us from achieving or maintaining market acceptance of current and future product candidates, if approved, and could significantly harm our business, results of operations and prospects.

***If we are not successful in discovering, developing and commercializing current and future product candidates, our ability to expand our business and achieve our strategic objectives may be impaired.***

Research programs designed to identify current and future product candidates may require substantial technical, financial and human resources, whether or not such efforts are successful. Our research programs may initially show promise in identifying current and future product candidates, yet fail to lead to clinical development or commercialization for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidate(s);
- competitors may develop alternatives that render our product candidate(s) obsolete;
- a product candidate(s) may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate(s) may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate(s) may not be accepted as safe and effective by regulatory authorities, participants, the medical community or third-party payors.

If we are unable to identify suitable compounds for preclinical and clinical development, we may not be able to obtain sufficient product revenues in future periods, which likely would result in significant harm to our financial position and adversely impact the price of the ADSs.

***Natural disasters, public health and other states of emergency, such as the COVID-19 outbreak, could adversely impact our business, including identifying current and future product candidates.***

Natural disasters, public health and other states of emergency affecting the countries in which we operate, or the global economic markets may have an adverse impact on our business. Quarantines, travel restrictions, shelter-in-place, nationalization efforts or similar government orders, such as lockdowns, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could have an indeterminate impact on our operations. Our suppliers or partners could also be disrupted by conditions related to infectious diseases, possibly resulting in disruption to our supply chain, collaborations or operations. If our suppliers, or other potential partners such as CMOs or contract research organizations (CROs) are unable or fail to fulfill their obligations to us for any reason, our ability to meet clinical and commercial supply demand for current and future product candidates may become impaired.

A resurgence of COVID-19 and actions taken to reduce its spread may also materially affect us economically. While the COVID-19 pandemic has generally subsided, there is a risk of the emergence of a new variant which could have potential economic impact and can significantly disrupt global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position.

Also, in the event of a pandemic, there is no guarantee that interruptions or delays in the operations of the FDA or other regulatory authorities in other jurisdictions will not impact the review and approval timelines for the marketing applications we may submit for current and future product candidates. 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 or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

The effect of the emergence of a new variant of COVID-19 or other broadly harmful pathogen is uncertain, and while we maintain business continuity plans, they might not adequately protect us. The extent to which COVID-19 or others broadly harmful pathogen or occurrence can negatively impact our business, financial condition and results of operations in the future will depend on future developments, which are highly uncertain and cannot be accurately predicted.

***Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns like the COVID-19 pandemic could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified product candidate(s) from being developed, or approved or commercialized in a timely manner or at all, which could negatively impact our business.***

The ability of the FDA, EMA and other regulatory agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's and EMA's ability to hire and retain key personnel and accept the payment of user fees, global health concerns like the COVID-19 pandemic and other events that may otherwise affect the ability of any regulatory agency such as the FDA and EMA to perform routine functions. Average review times at the FDA and EMA have fluctuated in recent years as a result. In addition, government funding of the FDA, EMA and other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA or other agencies may slow the time necessary for our product candidate(s) to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

***Coverage and reimbursement may not be available for current and future product candidates (if and when approved for commercial sale), which could make it difficult for us to sell such product candidates profitably.***

Market acceptance and sales of current and future product candidates will depend on coverage and reimbursement policies. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which products they will pay for and establish reimbursement levels. We cannot be sure that coverage and reimbursement will be available for current and future product candidates we may develop. Even if coverage is provided, we cannot be sure that the amount of reimbursement available, if any, will not reduce the demand for, or the price of, our product candidate(s). If reimbursement is not available or is available only at limited levels, we may not be able to successfully compete through sales of our proposed product candidate(s).

In the United States, no uniform policy of coverage and reimbursement for pharmaceutical 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 pharmaceutical products can differ significantly from payor to payor. Certain Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act marketplace and other private payor plans are required to include coverage for certain preventative services, including vaccinations recommended by the U.S. Centers for Disease Control's, or CDC's, Advisory Committee on Immunization Practices, or ACIP, without cost share obligations (i.e., co-payments, deductibles or co-insurance) for plan members. For Medicare beneficiaries, vaccines may be covered for reimbursement under either the Part B program or Part D depending on several criteria, including the type of vaccine and the beneficiary's coverage eligibility. If our vaccine candidate(s), once approved, is reimbursed only under the Part D program, physicians may be less willing to use our product candidate(s) because of the claims adjudication costs and time related to the claims adjudication process and collection of co-payments associated with the Part D program.

Outside the United States, certain countries, including a number of member states of the European Union, set prices and reimbursement for pharmaceutical products, with limited participation from the marketing authorization holders. We cannot be sure that such prices and reimbursement will be acceptable to us or our partners, if any. If the regulatory authorities in these jurisdictions set prices or reimbursement levels that are not commercially attractive for us, our revenues from sales by us, and the potential profitability of our product candidate(s), in those countries would be negatively affected. Additionally, some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. As a result, we might obtain marketing approval for a product candidate(s) in a particular country, but then may experience delays in the reimbursement approval of our product candidate(s) or be subject to price regulations that would delay our commercial launch of the product candidate(s), possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product candidate(s) in that particular country.

***Current and future legislation may increase the difficulty and cost for us and our partners, if any, to obtain marketing approval of and commercialize current and future product candidates and affect the prices we, or they, may obtain.***

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell current and future product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, was enacted in the United States. Among the provisions of the Affordable Care Act of importance to our potential product candidate(s), the Affordable Care Act: established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; expands eligibility criteria for Medicaid programs; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; created a new Medicare Part D coverage gap discount program; required certain Affordable Care Act marketplace and other private payor plans to include coverage for preventative services, including vaccinations recommended by the ACIP without cost share obligations (i.e., co-payments, deductibles or co-insurance) for plan members; established 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 established a Center for Medicare and Medicaid Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been judicial and congressional challenges to numerous aspects of the Affordable Care Act. By way of example, the 2017 Tax Reform Act included a provision repealing the individual mandate, effective January 1, 2019. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the Affordable Care Act is an essential and inseverable feature of the Affordable Care Act, and therefore because the mandate was repealed, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional, but remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the case. On November 10, 2020, the U.S. Supreme Court heard oral arguments regarding the constitutionality of the individual mandate. In June 2021, the U.S. Supreme Court ruled that the states that initially challenged the individual mandate did not have standing to sue. The U.S. Supreme Court did not rule on the constitutionality of the individual mandate. In addition, there may be other efforts to challenge, repeal or replace the Affordable Care Act. We are continuing to monitor any changes to the Affordable Care Act that, in turn, may potentially impact our business in the future.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011 and subsequent laws, which began in 2013 and will remain in effect through 2030, unless additional congressional action is taken. In addition, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. New laws may result in additional reductions in Medicare and other healthcare funding, which may materially adversely affect customer demand and affordability for our product candidates, if approved, and, accordingly, the results of our financial operations. We cannot predict whether future healthcare legislative or policy changes will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us, but we expect there will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care.

***We are subject to extensive and costly government regulation.***

Any current and future product candidate(s) we may develop will be, subject to extensive and rigorous domestic government regulation, including with respect to Europe, regulation by the EMA and

other relevant regional, national and local authorities, with respect to Israel, regulation by the Israeli Ministry of Health, and with respect to the U.S., regulation by the FDA, the CMS, other divisions of the U.S. Department of Health and Human Services, including its Office of Inspector General, the U.S. Department of Justice, the Departments of Defense and Veterans Affairs and, to the extent our product candidate(s) are paid for directly or indirectly by those departments, state and local governments and their respective foreign equivalents. The FDA regulates the research, development, preclinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, and import and export of pharmaceutical products under various regulatory provisions. Current and future product candidates we may develop, which will be tested and marketed abroad, will be subject to extensive regulation by foreign governments, whether or not we have obtained EMA, the Israeli Ministry of Health's approval and/or FDA approval. Such foreign regulation may be equally or more demanding than corresponding European, Israeli or U.S. regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing, and selling products. Our failure to comply with these regulations could result in, by way of example, significant fines, criminal and civil liability, product seizures, recalls, withdrawals, withdrawals of approvals, and exclusion and debarment from government programs. Any of these actions, including the inability of current and future product candidates to obtain and maintain regulatory approval, would have a materially adverse effect on our business, financial condition, results of operations and prospects.

***Our relationships with customers, third-party payors, physicians and healthcare providers will be subject to applicable anti-kickback, fraud and abuse, and other laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits.***

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of current and future product candidates. Our current and future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research and would market, sell and distribute our product candidate(s). As a biopharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include the following:

- the federal healthcare Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving, paying or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, arrangement, or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers, among others, on the other;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by, Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. In addition, the government may assert that a claim including items or services

resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. The False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (*e.g.*, public or private) and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious, or fraudulent statements in connection with the delivery of or payment for healthcare benefits, items or services relating to healthcare matters. Similar to the 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 federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively known as the Affordable Care Act, or ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, and its implementing regulations, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require the licensure of sales representatives; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information.

Efforts to ensure that our current and future business arrangements with third parties, and our business generally, continue to comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with any such laws and regulations. If our operations, including any arrangements with physicians and other healthcare providers, are found to be in violation of any such laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, reputational harm, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, additional reporting requirements, and/or the curtailment or restructuring of our operations, as well as additional reporting obligations oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. If we enter into business with any physicians or other healthcare providers or entities who are then found to not be in compliance with applicable laws, they may be subject to similar penalties.

***Changes in regulatory requirements and guidance or unanticipated events may occur during any future clinical trials we may conduct, which may result in necessary changes to clinical trial protocols, which could result in increased costs to us, delay our development timeline or reduce the likelihood of successful completion of such clinical trials.***

Changes in regulatory requirements and guidance or unanticipated events may occur during any clinical trials we may conduct may occur, as a result of which we may need to amend clinical trial protocols. Amendments may require us to resubmit our clinical trial protocols to IRBs for review and approval, which may adversely affect the cost, timing and successful completion of a clinical trial. If we experience delays in the completion of, or if we terminate, any future clinical trials we may conduct, the commercial prospects for current and future product candidates would be harmed and our ability to generate product revenue would be delayed, possibly materially.

***If we acquire or license additional technologies or product candidate(s), we may incur a number of additional costs, have integration difficulties and/or experience other risks that could harm our business and results of operations.***

We may acquire and in-license current and future product candidate(s) and technologies. Any current and future product candidate(s) or technologies we in-license or acquire will likely require additional development efforts prior to commercial sale, including extensive preclinical or clinical testing, or both, and approval by the FDA and applicable foreign regulatory authorities, if any. All product candidates are prone to risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate(s) or product candidate(s) developed based on in-licensed technology will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any current and future product candidate(s) that we develop based on acquired or licensed technology that is granted regulatory approval will be manufactured or produced economically, successfully commercialized or widely accepted or competitive in the marketplace. Moreover, integrating any newly acquired or in-licensed product candidate(s) could be expensive and time-consuming. If we cannot effectively manage these aspects of our business strategy, our business may not succeed.

**Risks Related to Our CDMO Business Unit**

***Initiating new business activities or strategies may expose us to new risks and may increase our costs associated with doing business.***

On September 6, 2023, we announced the launch of a new business unit named Scinai Bioservices to serve as a CDMO offering a multitude of services to support biotech companies through process development, as well as pilot and clinical GMP manufacturing. Initiating new business activities or strategies may expose us to new or increased financial, regulatory, reputational, and other risks. There is no guarantee that our business strategies will succeed. Such business strategies are important and necessary ways to grow our business and respond to changing circumstances in our industry; however, we cannot be certain that we will be able to manage the associated risks and compliance requirements effectively. Such risks include a lack of management-level personnel experienced with CDMO business management, increased administrative burden, increased logistical problems, increased credit and liquidity risk and increased regulatory scrutiny. See also " Risks Related to Our R&D Business Unit". We may encounter difficulties in managing our growth. Failure to manage our growth effectively will have a material adverse effect on our business, results of operations and financial condition".

***External competition from other CDMO providers may be harmful to our planned CDMO business.***

We face competition from other companies that are large, well-established manufacturers with financial, technical, research and development and sales and marketing resources that are significantly greater than ours. We also face competition from small biotech companies that are developing drugs at early stages that may choose to self-manufacture rather than utilize a contract manufacturer. To be successful, we will need to convince potential clients that our overall value proposition is superior to the one that could be achieved through internal drug development and manufacturing. Our ability to achieve this and to successfully compete against other manufacturers will depend, in large part, on our success in developing

processing technologies that improve the efficiency and reduce the cost associated with drug development projects. If we are unable to successfully demonstrate our competitive advantages, we may not be able to compete against other CDMOs.

***CDMO services are highly complex and failure to provide quality and timely services to our CDMO clients could adversely impact our business.***

The CDMO services we offer can be highly complex, due in part to strict regulatory requirements and the inherent complexity of the services provided. A failure of our quality control systems in our facilities could cause problems in connection with facility operations for a variety of reasons, including equipment malfunction, viral contamination, failure to follow specific manufacturing instructions, protocols and standard operating procedures, problems with raw materials or environmental factors. Such issues could affect production of a single manufacturing run or manufacturing campaigns, requiring the destruction of products, or could halt manufacturing operations altogether. In addition, any failure to meet required quality standards may result in our failure to timely deliver products to our clients which, in turn, could damage our reputation for quality and service. Any such incident could, among other things, lead to increased costs, lost revenue, reimbursement to clients for lost drug substances, damage to and possibly termination of client relationships, time and expense spent investigating and remediating the cause and, depending on the cause, similar losses with respect to other manufacturing runs. In addition, such issues could subject us to litigation, the cost of which could be significant.

***Problems may arise during the production of our products and product candidates, as well as those we produce for our CDMO clients, due to the complexity of the processes involved in their development, manufacturing and shipment or other factors. Significant delays in product manufacturing or development and our ability to produce sufficient quantities to meet the needs of our clients could cause delays in recognizing revenues, which would harm our business, financial condition, operating results and cash flows.***

The majority of our products and product candidates are VHH antibody fragments that are also known as nanobodies. Manufacturing VHH antibody fragments, especially in large quantities, is complex. The products must be made consistently and in compliance with a clearly defined manufacturing processes. Problems during manufacturing may arise for a variety of reasons, including problems with raw materials, equipment malfunction and failure to follow specific protocols and procedures. Slight deviations anywhere in the manufacturing process, including obtaining materials, maintaining master cell banks and preventing genetic drift, cell growth, fermentation, contamination including from particulates among other things, filtration, filling, labeling, packaging, storage and shipping, potency and stability issues and other quality control testing, may result in lot failures or manufacturing shut-downs, delays in the release of lots, product recalls, spoilage or regulatory action. Such deviations may require us to revise manufacturing processes or change manufacturers. Additionally, as our equipment ages, it will need to be replaced, which has the potential to result in similar consequences. Success rates can also vary dramatically at different stages of the manufacturing process, which can reduce yields and increase costs. From time to time, we may experience deviations in the manufacturing process that may take significant time and resources to resolve and, if unresolved, may affect manufacturing output and could cause us to fail to satisfy client orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in our clinical trials, result in litigation, or other restrictions on the marketing or manufacturing of a product, any of which could be costly to us, damage our reputation and negatively impact our business. Regulatory action, including the issuance of Forms FDA 483 and warning letters, can also have an impact.

Additionally, if changes are made to the manufacturing process, we may be required to provide the relevant regulatory agency with pre-clinical and clinical data showing the comparable identity, strength, quality, purity or potency of any impacted products before and after the changes.

We may be required to ship our VHH antibody fragment drug candidates to clinical trial facilities at a prescribed temperature range and variations from that temperature range could result in loss of product and could significantly and adversely impact our drug development program timelines, which could harm our business, financial condition, operating results and cash flows.

In addition, we may not be able to produce sufficient quantities to meet the rapidly changing demand or specifications of our clients on the desired timeframe, if at all. Our inability to produce sufficient quantities to meet the demand or specifications of our clients or the inability to timely obtain regulatory authorization to produce the products or product candidates of our clients could also harm our business, financial condition, operating results and cash flows.

**Risks Related to Our R&D Business Unit**

***The members of our management team and certain consultants are important to the efficient and effective operation of our business, and we may need to attract and retain additional management and experts. Our limited financial resources may hinder the successful retention of our management and consulting team and adding additional experts, which could have a material adverse effect on our business, financial condition or results of operations.***

Our executive officers, management team and technical personnel, as well as certain consultants, are important to the efficient and effective operation of our business, particularly Mr. Amir Reichman, our Chief Executive Officer, Dr. Tamar Ben-Yedidia, our Chief Scientific Officer, and Mr. Elad Mark, our Chief Operating Officer. The early stage of our NanoAbs program creates uncertainty about our prospects and may make it more difficult to attract and retain qualified executives and other key personnel.

***We are a developmental stage biopharmaceutical company with no product candidate(s) approved for marketing by regulatory agencies such as FDA, which makes it difficult to assess our future viability.***

We are a developmental stage biopharmaceutical company with a limited operating history. We have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in rapidly evolving fields, particularly in the pharmaceutical area. For example, to execute any future business plan, we may need to successfully:

- execute development activities;
- obtain required FDA and applicable foreign regulatory authorizations for the development and commercialization of current and future product candidates;
- maintain, leverage and expand our intellectual property portfolio;
- build and maintain robust sales, distribution and marketing capabilities, either on our own or in collaboration with strategic partners;
- gain market acceptance for our product candidate(s);
- develop and maintain any strategic relationships we elect to enter into; and
- manage our spending as costs and expenses increase due to drug discovery, preclinical development, clinical trials, regulatory approvals and commercialization.

If we are unsuccessful in accomplishing these objectives, we may not be able to develop any current and future product candidate(s), raise capital, expand our business or continue our operations.

***We face significant competition. If we cannot successfully compete with new or existing product candidate(s), our marketing and sales will suffer and we may never be profitable.***

We compete against fully integrated pharmaceutical and biopharmaceutical companies and smaller companies that are collaborating with pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. In addition, many of these competitors, either alone or together with their strategic partners, operate larger research and development programs than we do, and have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing immuno-modulating products;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA approvals and addressing various regulatory matters and obtaining other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

Generally, our competitors currently include large fully integrated pharmaceutical companies such as Sanofi-Pasteur, GlaxoSmithKline and other companies as well as companies and academic research institutes in various developmental stages attempting to develop COVID-19 therapies, such as Invivyd (formerly known as Adagio),Vir, and Exevir., or IL-17 therapies, such as UCB, Moonlake, and others. If our competitors develop and commercialize products faster than we do, or develop and commercialize products that are superior to our product candidate(s), our commercial opportunities will be reduced or eliminated. Our competitors may succeed in developing and commercializing products earlier and obtaining regulatory approvals from the FDA and foreign regulatory authorities more rapidly than we do. Our competitors may also develop products or technologies that are superior to those we are developing and render our product candidate(s) obsolete or non-competitive. If we cannot successfully compete with new or existing product candidate(s), our marketing and sales will suffer and we may never be profitable.

The extent to which our product candidate(s) achieves market acceptance will depend on competitive factors, many of which are beyond our control. Competition in the biotechnology and biopharmaceutical industry is intense and has been accentuated by the rapid pace of technology development. Our competitors also compete with us to:

- attract parties for acquisitions, joint ventures or other collaborations;
- license proprietary technology that is competitive with current and future product candidates;
- attract funding; and
- attract and hire scientific talent and other qualified personnel.

***We may be subject to legal proceedings and/or to product liability lawsuits.***

We could incur substantial costs and be required to limit commercialization in connection with product liability claims relating to current and future product candidates, which may result in substantial losses.

Current and future product candidates could cause adverse events, including injury, disease or adverse side effects. These adverse events may not be observed in clinical trials, but may nonetheless occur in the future. If any of these adverse events occur, they may render current and future product candidates ineffective or harmful in some participants, and any future sales would suffer, materially adversely affecting our business, financial condition and results of operations.

In addition, potential adverse events caused by current and future product candidates could lead to product liability lawsuits. If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit the marketing and commercialization of any current and future product candidate(s). Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. We may not be able to avoid product liability claims. For example, changes in laws outside the U.S. are expanding our potential liability for injuries that occur during clinical trials. Product liability insurance is expensive, subject to deductibles and coverage limitations, and may not be available in the amounts that we desire for a price we are willing to pay. Product liability insurance for the pharmaceutical and biotechnology industries is generally expensive, if available at all. If, at any time, we are unable to obtain sufficient

insurance coverage on reasonable terms or to otherwise protect against potential product liability claims, we may be unable to clinically test, market or commercialize any current and future product candidate(s). A successful product liability claim brought against us in excess of our insurance coverage, if any, may cause us to incur substantial liabilities, and, as a result, our business, liquidity and results of operations would be materially adversely affected. In addition, the existence of a product liability claim could affect the market price of the ADSs.

***If our employees commit fraud or other misconduct, including noncompliance with regulatory standards and requirements, and insider trading, our business may experience serious adverse consequences.***

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures: to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state health-care fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Our board of directors adopted a Code of Ethics. However, it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

In addition, during the course of our operations, our directors, executives and employees may have access to material, non-public information regarding our business, our results of operations or potential transactions we are considering. If a director, executive or employee was to be investigated, or an action was to be brought against a director, executive or employee for insider trading, it could have a negative impact on our reputation and the market price of the ADSs. Such a claim, with or without merit, could also result in substantial expenditures of time and money, and divert attention of our management team from other tasks important to the success of our business.

***We may encounter difficulties in managing our growth. Failure to manage our growth effectively will have a material adverse effect on our business, results of operations and financial condition.***

We may not be able to successfully grow and expand. Successful implementation of any future business plan will require management of growth, including potentially rapid and substantial growth, which will result in an increase in the level of responsibility for management personnel and place a strain on our human and capital resources. To manage growth effectively, we will be required to continue to implement and improve our operating and financial systems and controls to expand, train and manage our employee base. Our ability to manage our operations and growth effectively will require us to continue to expend funds to enhance our operational, financial and management controls, reporting systems and procedures, and to attract and retain sufficient talented personnel. If we are unable to scale up and implement improvements to our control systems in an efficient or timely manner, or if we encounter deficiencies in existing systems and controls, then we will not be able to successfully commercialize any current and future product candidate(s). Failure to attract and retain sufficient talented personnel will further strain our human resources and could impede our growth or result in ineffective growth. Moreover, the management, systems and controls currently in place or to be implemented may not be adequate for such growth, and the steps we have taken to hire personnel and to improve such systems and controls might not be sufficient. If we are unable to manage our growth effectively, it will have a material adverse effect on our business, results of operations and financial condition.

***If we are unable to obtain adequate insurance, our financial condition could be adversely affected in the event of uninsured or inadequately insured loss or damage. Our ability to effectively recruit and***

***retain qualified officers and directors could also be adversely affected if we experience difficulty in obtaining adequate directors' and officers' liability insurance.***

Our business will expose us to potential liability that results from risks associated with conducting clinical trials of current and future product candidates. A successful clinical trial liability claim, if any, brought against us could have a material adverse effect on our business, prospects, financial condition and results of operations even though clinical trial insurance is successfully maintained or obtained. The current and planned insurance coverages may only mitigate a small portion of a substantial claim against us.

In addition, we may be unable to maintain sufficient insurance as a public company to cover liability claims made against our officers and directors. If we are unable to adequately insure our officers and directors, we may not be able to retain or recruit qualified officers and directors to manage the Company.

***Recent disruptions in the financial markets and economic conditions could affect our ability to raise capital.***

In recent years, the U.S. and global economies suffered dramatic downturns as the result of a deterioration in the credit markets and related financial crises as well as a variety of other factors including, among other things, the COVID-19 pandemic, extreme volatility in security prices, severely diminished liquidity and credit availability, ratings downgrades of certain investments and declining valuations of others. While the financial markets have improved, they are still somewhat unstable, and a resurgence of COVID-19 or similar disruptions or the return of adverse economic conditions may cause a significant impact on our ability to raise capital, if needed, on a timely basis and on acceptable terms or at all.

***We may be subject to extensive environmental, health and safety, and other laws and regulations in multiple jurisdictions.***

Our business involves the controlled use, directly or indirectly through our service providers, of hazardous materials, various biological compounds and chemicals; therefore, we, our agents and our service providers may be subject to various environmental, health and safety laws and regulations, including those governing air emissions, water and wastewater discharges, noise emissions, the use, management and disposal of hazardous, radioactive and biological materials and wastes and the cleanup of contaminated sites. The risk of accidental contamination or injury from these materials cannot be eliminated. If an accident, spill or release of any regulated chemicals or substances occurs, we could be held liable for resulting damages, including for investigation, remediation and monitoring of the contamination, including natural resource damages, the costs of which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials and chemicals. Although we maintain workers' compensation insurance to cover the costs and expenses that may be incurred because of injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. Additional or more stringent federal, state, local or foreign laws and regulations affecting our operations may be adopted in the future. We may incur substantial capital costs and operating expenses and may be required to obtain consents to comply with any of these or certain other laws or regulations and the terms and conditions of any permits or licenses required pursuant to such laws and regulations, including costs to install new or updated pollution control equipment, modify our operations or perform other corrective actions at our respective facilities or the facilities of our service providers.

***Governments may impose strict price controls, which may adversely affect our revenues, if any.***

In some countries, including the countries comprising the European Union (the "EU"), the pricing of pharmaceuticals and certain other therapeutics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate(s) to other available therapies. If reimbursement of our product candidate(s) is unavailable or

limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

***Our internal computer systems, or those used by our contractors or consultants, may fail or experience security breaches or other unauthorized or improper access.***

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to privacy and information security incidents, such as data breaches, damage from computer viruses and unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication, electrical failures, cyber-attacks or cyber-intrusions over the internet and attachments to emails. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we will rely on third parties to conduct clinical trials for, and manufacture, current and future product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. Unauthorized disclosure of sensitive or confidential data, including personally identifiable information, whether through a breach of computer systems, systems failure, employee negligence, fraud or misappropriation, or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third parties, could result in negative publicity, legal liability and damage to our reputation. Unauthorized disclosure of personally identifiable information could also expose us to sanctions for violations of data privacy laws and regulations around the world. To the extent that any disruption or security breach result 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 candidate(s) could be delayed.

As we become more dependent on information technologies to conduct our operations, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, may increase in frequency and sophistication. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data and these risks apply both to us, and to third parties on whose systems we rely for the conduct of our business. Because the techniques used to obtain unauthorized access, disable or degrade service or sabotage systems change frequently and often are not recognized until launched against a target, we and our partners may be unable to anticipate these techniques or to implement adequate preventative measures. Further, we do not have any control over the operations of the facilities or technology of our cloud and service providers, including any third party vendors that collect, process and store personal data on our behalf. Our systems, servers and platforms and those of our service providers may be vulnerable to computer viruses or physical or electronic break-ins that our or their security measures may not detect. Individuals able to circumvent such security measures may misappropriate our confidential or proprietary information, disrupt our operations, damage our computers or otherwise impair our reputation and business. We may need to expend significant resources and make significant capital investment to protect against security breaches or to mitigate the impact of any such breaches. There can be no assurance that we or our third party providers will be successful in preventing cyber-attacks or successfully mitigating their effects. To the extent that any disruption or security breach were to result 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 and commercialization of our current and future product candidate(s) could be delayed.

***Failure to comply with current or future federal, state and foreign laws and regulations and industry standards relating to privacy and data protection laws could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and adverse publicity and could negatively affect our operating results and business.***

We and our partners and third-party providers may be subject to federal, state and foreign data privacy and security laws and regulations. In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (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 and third-party providers.

In many jurisdictions, enforcement actions and consequences for noncompliance are rising. In the United States, these include enforcement actions in response to rules and regulations promulgated under the authority of federal agencies and state attorneys general and legislatures and consumer protection agencies. In addition, privacy advocates and industry groups have regularly proposed, and may propose in the future, self-regulatory standards that may legally or contractually apply to us. If we fail to follow these security standards, even if no customer information is compromised, we may incur significant fines or experience a significant increase in costs. Many state legislatures have adopted legislation that regulates how businesses operate online, including measures relating to privacy, data security and data breaches. Laws in all 50 states require businesses to provide notice to customers whose personally identifiable information has been disclosed as a result of a data breach. The laws are not consistent, and compliance in the event of a widespread data breach is costly. States are also constantly amending existing laws, requiring attention to frequently changing regulatory requirements. Furthermore, California enacted the California Consumer Privacy Act (the "CCPA"), which gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. 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.

Foreign data protection laws, including EU General Data Protection Regulation (the "GDPR"), may also apply to health-related and other personal information obtained outside of the United States. The GDPR, which came into effect on May 25, 2018, introduced new data protection requirements in the European Union, as well as potential fines for noncompliant companies of up to the greater of €20 million or 4% of annual global revenue. The regulation imposes numerous new requirements for the collection, use and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, extensive new internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information (e.g., the right to access, correct and delete their data). 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. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union.

Compliance with U.S. and foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure by us or our partners and third-party providers to comply with U.S. and foreign data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, results of operation and financial condition.

**Risks Related to Dependence on Third Parties**

***Our NanoAbs program is based on an exclusive license from MPG and UMG, and we could lose our rights to this license if a dispute with MPG and/or UMG arises or if we fail to comply with the financial and other terms of the license.***

We license the core intellectual property for our NanoAbs program from MPG and UMG under exclusive license agreements, pursuant to which we received an exclusive worldwide license for the

development and commercialization of COVID-19 NanoAbs and for the IL-17 NanoAbs based on certain patents and intellectual property owned by MPG and UMG and related thereto. Pursuant to the terms of the license agreement, unless earlier terminated in accordance with the provisions thereof, the license agreement will expire on a product-by-product and country-by-country basis upon the later of (i) the expiration or abandonment of the patent rights that relate to such product in such country and (ii) ten years from the date of first commercial sale of such product in such country. However, MPG is entitled to terminate the exclusivity rights or to terminate the license agreement if, among other things, the Company fails to submit an IND application by a certain date or if the patent rights licensed pursuant to the License Agreement are invalidated. We have the right to license nanobodies against certain other molecular targets on the same terms described above.

If MPG terminates the license agreement, or licenses to a third party the intellectual property it had licensed to us pursuant to this license agreement, or if any dispute arises with respect to our arrangement with MPG, such dispute may disrupt our operations and would likely have a material and adverse impact on us if resolved in a manner that is unfavorable to us. Our NanoAbs program is based on the intellectual property licensed under the license agreement, and if the license agreement is terminated prior to its expiration, it could have a material adverse effect on our business, prospects and results of operations.

***We rely on MPG to create and provide for our IL-17 NanoAbs program and any additional NanoAbs for our COVID-19 NanoAbs program and expect to rely on them for other NanoAbs programs that we may initiate in the future.***

We rely on MPG to create and provide for our IL-17 NanoAbs program and any additional NanoAbs for our COVID-19 NanoAbs program and expect to rely on them for other NanoAbs programs that we may initiate in the future. If the supply of NanoAbs is disrupted or delayed, we will not be able to complete, or may be delayed in our efforts to, successfully develop and commercialize our current or future product candidates. There is no guarantee that we will be successful in in in-licensing additional NanoAbs from MPG and UMG, or developing, and/or commercializing any of our NanoAbs

***If we were to conduct clinical trials, we would rely on third parties to conduct any such clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.***

We will rely on third parties such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct any future clinical trials on our behalf. Any of these third parties may terminate their engagement with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities.

Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. We remain responsible for ensuring that our clinical trial is conducted in accordance with the requirements of the relevant regulator, and failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, third parties that we rely on for our clinical development activities may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any current and future product candidate(s). Our product development costs will increase if we experience delays in testing or obtaining marketing approvals.

***A disruption to our GMP biologics manufacturing facility in Jerusalem could impede our ability to advance our NanoAbs programs and deliver our CDMO services, which could adversely affect our business.***

Our current manufacturing facility contains highly specialized equipment and materials and utilizes complicated production processes developed over a number of years, which would be difficult, time-consuming, and costly to duplicate or, though a remote risk, may be impossible to duplicate. We do

not have any redundant manufacturing facilities. If this facility were damaged or destroyed, or otherwise subject to disruption, including contamination, it would require substantial lead-time to replace such manufacturing capabilities and could cause costly delays in our R&D activities and in the performance of our CDMO services. In such event, we would be forced to identify and rely entirely on third-party contract manufacturers for an indefinite period of time, which we may not be able to do in a timely manner and would further increase our production costs. Any disruptions or delays at our facility or its failure to meet regulatory compliance would significantly impair our ability to advance our NanoAbs program and deliver our CDMO services, which would result in increased costs and losses and adversely affect our business and results of operations.

***Use of third parties to manufacture current and future product candidate(s) may increase the risk that we will not have sufficient quantities of such product candidate(s) at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.***

Our GMP biologics manufacturing facility in Jerusalem is capable of manufacturing an annual supply of current and future product candidate(s) suitable for regulatory or other similar uses. However, we may also rely on a third party CMO for commercial supply of current and future product candidates.

Reliance on a third party CMO entails risks, including:

- Reliance on third party for regulatory compliance and quality assurance;
- The possible breach of the manufacturing agreement by the third party;
- The possible failure to manufacture sufficient quantities of current and future product candidates due to reasons outside of the reasonable control of the third party;
- The possible misappropriation of our proprietary information, including our know-how; and
- The possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

A CMO may not be able to comply with cGMP regulations or similar regulatory requirements outside of the U.S. Our failure, or the failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidate(s), operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidate(s).

***We may not obtain the necessary materials for the performance of any future clinical trials in the U.S. or other countries around the world that we may conduct.***

Clinical trials we may conduct in the future may involve obtaining materials and information that may not currently be in our possession and that we rely on suppliers and manufacturers to provide. It is possible that the FDA or any other relevant regulatory body will request that we provide materials or information that are not in our possession at that time before allowing us to proceed with any proposed clinical trials.

**Risks Related to Our Intellectual Property**

***If we fail to adequately protect, enforce or secure rights to the patents which we own or that were licensed to us or any patents we may own or license in the future, the value of our intellectual property rights would diminish and our business and competitive position would suffer.***

Our success, competitive position and future revenues, if any, depend in part on our ability to obtain and successfully leverage intellectual property covering our product candidate(s), know-how, methods, processes and other technologies, to protect our trade secrets, to prevent others from using our intellectual property and to operate without infringing the intellectual property rights of third parties.

The risks and uncertainties that we face with respect to our intellectual property rights include, but are not limited to, the following:

- the degree and range of protection any patents will afford us against competitors;
- the patents concerning our business activities were not registered in all countries and therefore our patent protection may be lacking in some territories;
- if and when patents will be issued;
- whether or not others will obtain patents claiming aspects similar to those covered by our own or licensed patents and patent applications;
- we may be subject to interference proceedings;
- we may be subject to opposition or post-grant proceedings in foreign countries;
- any patents that are issued may not provide meaningful protection;
- we may not be able to develop additional proprietary technologies that are patentable;
- other companies may challenge patents licensed or issued to us or our customers;
- other companies may independently develop similar or alternative technologies, or duplicate our technologies;
- other companies may design around technologies we have licensed or developed;
- enforcement of patents is complex, uncertain and expensive; and
- we may need to initiate litigation or administrative proceedings that may be costly whether we win or lose.

If patent rights covering our product candidate(s) and methods are not sufficiently broad, they may not provide us with any protection against competitors with similar products and technologies. Furthermore, if the United States Patent and Trademark Office (the "USPTO") or any foreign patent office issue patents to us or our licensors, others may challenge the patents or design around the patents, or the patent office or the courts may invalidate the patents. An adverse determination in any opposition, derivation, revocation, re-examination, post-grant and inter parties review or interference proceedings or foreign equivalent, or litigation, challenging our patent rights or the patent rights of others could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Such proceedings and any other patent challenges may result in loss of patent rights, loss of exclusivity, loss of priority or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection of our technology and product candidate(s). Thus, any patents we own or license from or to third parties may not provide any protection against our competitors. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Moreover, there could be public announcements of the results of hearings, motions or other developments related to any of the foregoing proceedings. If securities analysts or investors perceive those results to be negative, it could cause the price of the ADSs to decline. Any of the foregoing could harm our business, results of operations and financial condition.

We cannot be certain that patents will be issued as a result of any pending applications, and we cannot be certain that any of our issued patents or patents licensed from MPG (or any other third-party in the future) will give us adequate protection from competing products. Further, even if our owned or licensed patent applications issue as patents, the issuance of any such patents is not conclusive as to their inventorship, scope, validity or enforceability and such patents may be challenged, invalidated, narrowed or held to be unenforceable.

We may be subject to a third-party pre-issuance submission of prior art to the USPTO or equivalent foreign bodies. In addition, since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to make our inventions or to file patent applications covering those inventions.

Moreover, some of our owned or in-licensed patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, who could market competing products and technology. In addition, we may need the cooperation of any such co-owners in order to enforce such patents against third parties, and such cooperation may not be provided to us.

It is also possible that others may obtain issued patents that could prevent us from commercializing our product candidate(s) or require us to obtain licenses requiring the payment of significant fees or royalties in order to enable us to conduct our business. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These 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. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. 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 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. As to those patents that we have licensed, our rights depend on maintaining our obligations to the licensor under the applicable license agreement, and we may be unable to do so.

In addition to patents and patent applications, we depend upon proprietary know-how to protect our proprietary technology. We require our employees, consultants, advisors and partners to enter into confidentiality agreements that prohibit the disclosure of confidential information to any other parties. We also require our employees and consultants to disclose and assign to us their ideas, developments, discoveries and inventions. These agreements may not, however, provide adequate protection for our know-how or other proprietary information in the event of any unauthorized use or disclosure.

***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 for noncompliance with these requirements.***

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to office actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

***Costly litigation may be necessary to protect our intellectual property rights and we may be subject to claims alleging the violation of the intellectual property rights of others.***

We may face significant expense and liability as a result of litigation or other proceedings relating to patents and other intellectual property rights of others. In the event that another party has also filed a patent application or been issued a patent relating to an invention or technology claimed by us in pending applications, we may be required to participate in an interference proceeding declared by the USPTO to determine priority of invention, which could result in substantial uncertainties and costs for

us, even if the eventual outcome is favorable to us. We, or our licensors, also could be required to participate in interference proceedings involving issued patents and pending applications of another entity. An adverse outcome in an interference proceeding could require us to cease using the technology or to license rights from prevailing third parties.

The cost to us of any patent litigation or other proceeding relating to our licensed patents or patent applications, even if resolved in our favor, could be substantial and could divert management's resources and attention. Competitors and other third parties may infringe, misappropriate or otherwise violate our issued patents or other intellectual property or the patents or other intellectual property of our licensors. Our ability to enforce our patent protection could be limited by our financial resources, and may be subject to lengthy delays. In addition, our patents or the patents of our licensors may become involved in inventorship or priority disputes. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our patents are invalid or unenforceable. In a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology. An adverse result in any litigation proceeding could put one or more of our owned or licensed patents at risk of being invalidated, held unenforceable or interpreted narrowly. We may find it impractical or undesirable to enforce our intellectual property against some third parties.

A third party may claim that we are using inventions claimed by their patents and may go to court to stop us from engaging in our normal operations and activities, such as research, development and the sale of any current and future product candidate(s). Such lawsuits are expensive and would consume time and other resources. There is a risk that a court will decide that we are infringing the third party's patents and will order us to cease the activities claimed by the patents, including to cease commercializing the infringing technology or product candidate(s), redesign our product candidate(s) or processes to avoid infringement, which may be impossible or require substantial time and monetary expenditure, or obtain licenses (which may not be available on commercially reasonable terms or at all). In addition, there is a risk that a court will order us to pay the other party damages for having infringed their patents.

There is no guarantee that any prevailing patent owner would offer us a license so that we could continue to engage in activities claimed by the patent, or that such a license, if made available to us, could be acquired on commercially acceptable terms. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties and other fees. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. In addition, third parties may, in the future, assert other intellectual property infringement claims against us with respect to our product candidate(s), technologies or other matters. Any claims of infringement asserted against us, whether or not successful, may have a material adverse effect on us. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims could result in substantial costs and diversion of management resources, which could harm our business. 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 or in-license needed technology or other product candidate(s). There could also be public announcements of the results of the hearing, motions or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of the ADSs to decline. Any of the foregoing events could harm our business, financial condition, results of operations and prospects.

***We rely on confidentiality agreements that could be breached and may be difficult to enforce, which could result in third parties using our intellectual property to compete against us.***

Although we believe that we take reasonable steps to protect our intellectual property, including the use of agreements relating to the non-disclosure of confidential information to third parties, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas,

developments, discoveries and inventions of our employees and consultants while we employ them, the agreements can be difficult and costly to enforce. Although we seek to enter into these types of agreements with our contractors, consultants, advisors and research and other partners, to the extent that employees and consultants utilize or independently develop intellectual property in connection with any of our projects, disputes may arise as to the intellectual property rights associated with current and future product candidates. If a dispute arises, a court may determine that the right belongs to a third party. In addition, enforcement of our rights can be costly and unpredictable. We also rely on trade secrets and proprietary know-how that we seek to protect in part by confidentiality agreements with our employees, contractors, consultants, advisors or others. 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. Despite the protective measures we employ, we still face the risk that:

- these agreements may be breached;
- these agreements may not provide adequate remedies for the applicable type of breach;
- our proprietary know-how will otherwise become known; or
- our competitors will independently develop similar technology or proprietary information.

***International patent protection is particularly uncertain, and if we are involved in opposition proceedings in foreign countries, we may have to expend substantial sums and management resources.***

Patent law outside the United States may be different than in the United States. Further, the laws of some foreign countries, such as China where certain patents owned or licensed by us were granted, may not protect our intellectual property rights to the same extent as the laws of the United States, if at all. A failure to obtain sufficient intellectual property protection in any foreign country could materially and adversely affect our business, results of operations and future prospects. Moreover, we may participate in opposition proceedings to determine the validity of our foreign patents or our competitors' foreign patents, which could result in substantial costs and divert management's resources and attention. Additionally, due to uncertainty in patent protection law, we have not filed patent applications in many countries where significant markets exist.

***Intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds that are the same as or similar to current and future product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or any future strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;

- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- we may not develop additional proprietary technologies that are patentable; and

- the patents of others may have an adverse effect on our business.

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

We may be subject to claims that employees, partners or other third parties who were involved in the development of intellectual property for the Company have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who were involved in the development of intellectual property for the Company. Litigation may be necessary to defend against these and other claims challenging inventorship. 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.

***We may become subject to claims for remuneration or royalties for assigned service invention rights by our employees, which could result in litigation and adversely affect our business.***

A significant portion of our intellectual property has been and may in the future be developed by our employees in the course of their employment for us. Under the Israeli Patents Law, 5727-1967 (the "Patents Law"), inventions conceived by an employee in the course and as a result of or arising from his or her employment with a company are regarded as "service inventions," which belong to the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. The Patents Law also provides that if there is no such agreement between an employer and an employee, the Israeli Compensation and Royalties Committee (the "Committee"), a body constituted under the Patent Law, shall determine whether the employee is entitled to remuneration for his inventions. Decisions by the Committee have created uncertainty in this area, as it held that employees may be entitled to remuneration for their service inventions despite having specifically waived any such rights. However, a later decision by the Committee held that such right can be waived by the employee. The Committee further held that an explicit reference to the waived right is not necessary in every circumstance in order for the employee's waiver of such right to be valid. Such waiver can be formalized in writing or orally or be implied by the actions of the parties in accordance with the rules of interpretation of Israeli contract law. We generally enter into assignment-of-invention agreements with our employees pursuant to which such individuals assign to us all rights to any inventions created in the scope of their employment or engagement with us. Although our employees have agreed to assign to us service invention rights, we may face claims demanding remuneration in consideration for assigned inventions.

***We may receive less revenue from any current and future product candidate(s) if any of our employees successfully claim for compensation for their work in developing our intellectual property, which in turn could impact our future profitability.***

Our employees may have been previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. Litigation may be necessary to defend against these claims. If we fail in prosecuting or 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 prosecuting or defending against such claims, litigation could result in substantial costs, delay development of our product candidate(s) and be a distraction to management. Any of the foregoing events would harm our business, prospects and results of operations.

***Patent terms may be inadequate to protect our competitive position on our product candidate(s) 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 candidate(s) are obtained, once the patent life has expired for a product candidate(s), we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidate(s), patents protecting such product candidate(s) might expire before or shortly after such product candidate(s) are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidate(s) similar or identical to ours.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidate(s), 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 one or more of our foreign patents may be eligible for patent term extension under similar legislation, for example, in the European Union. In the United States, 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, there are no assurances that the USPTO or any comparable foreign regulatory authority or national patent office will grant such extensions, in whole or in part. For example, 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(s) will be shortened, and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable product candidate(s) 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 the case, and our competitive position, business, financial condition, results of operations and prospects could be materially harmed.

**Risks Related to Our Operations in Israel**

***We conduct most of our operations in Israel. Conditions in Israel, including the recent attack by Hamas from the Gaza Strip and Israel's war against it, may affect our operations.***

Because we are incorporated under the laws of the State of Israel and most of our operations are conducted in Israel, our business and operations are directly affected by economic, political, geopolitical and military conditions in Israel. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its neighboring countries and terrorist organizations active in the region. These conflicts have involved missile strikes, hostile infiltrations and terrorism against civilian targets in various parts of Israel. In addition, Israel faces threats from more distant neighbors, in particular, Iran. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations and could make it more difficult for us to raise capital..

Parties with whom we do business may decline to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary in order to meet our business partners face to face. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements.

In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in extensive deaths, injuries and kidnapping of civilians and soldiers. Following the attack, Israel's security cabinet declared war against Hamas and a military campaign against this terrorist organization commenced in parallel to its continued rocket and terror attacks. Moreover, the clash between Israel and Hezbollah in Lebanon may escalate in the future into a greater regional conflict. Additionally, Yemeni rebel group, the Houthis, have launched series of attacks on global shipping routes in the Red Sea, causing disruptions of supply chain. These geopolitical developments may adversely affect our ability to continue carrying out various administrative, research, operational and commercial functions and activities both in Israel and globally.

Our R&D business unit is currently focused on advancing a novel VHH antibody for the treatment of psoriasis and related diseases. We plan to commence a pre-clinical toxicology study in Q3/4 2024. The production of the drug substance and drug product batches required for the studies is done at our site located in Jerusalem, Israel. As such, an escalation of the conflict in Gaza or its expansion to include the northern border of Israel could potentially impact the studies. Risks include delays in operations due to missile attacks and/or difficulty in recruiting additional employees or service providers due to their service in the reserve forces of the Israel Defense Forces (the "IDF"), the national military of Israel.

We currently do not anticipate any material risk that the drug production for the studies will not be to be produced in Jerusalem, Israel. In the event we are not able to perform the drug production ourselves, we can approach alternative suppliers to perform the production. If we need to approach alternative suppliers, our pre-clinical trial could be delayed. A delay or disruption in our pre-clinical trial could impact the value of our securities, require us to raise additional capital, reduce operating expenses, including by reducing headcount, and/or limit or terminate our product development activities.

In October 2023, our CDMO business unit signed its first contract to provide R&D services to a biotech client and since then we have signed additional contracts with other clients, and we are in advanced contract discussions with several other potential clients. Although we have not seen that the ongoing conflict has affected this business to date, there can be no assurances that potential clients will not delay their engagement with us or not engage us for CDMO services due to conflict or that the conflict will not otherwise have a material adverse effect on us or our operations in the future.

The IDF is a conscripted military service, subject to certain exceptions. Since October 7, 2023, the IDF has called up more than 350,000 of its reserve forces to serve. We currently have 30 employees, all of whom reside in Israel, consisting of 10 management employees and 22 non-management employees. Our CEO was called in Q4 2023 for reserve service near his home to be "on-call" for emergency situations. During that time, he continued to perform his work duties partially remotely and partially from our Company's offices in Jerusalem. Such reserve duty has not materially affected the Company's operations. In addition, two of our non-management employees who do not perform critical functions have been called to reserve military service in the IDF with both having been released. It is possible that there will be further military reserve duty call-ups in the future, which may affect our business and disrupt our operations due to a shortage of skilled labor and loss of institutional knowledge, and necessary mitigation measures we may take to respond to a decrease in labor availability. These measures may include overtime and third-party outsourcing. These possible effects on our business may adversely impact our results of operations, liquidity or cash flows.

Additionally, shelter-in-place and work-from-home measures, government-imposed restrictions on movement and travel and other precautions taken to address the ongoing conflict may temporarily disrupt our management and employees' ability to effectively perform their daily tasks.

In addition, as a result of the war, the international rating agency, Moody's, has cut Israel's credit rating from A1 to A2 and has also lowered Israel's outlook from stable to negative, stating that it sees a possible further downgrade in the future. Lowered credit rating of Israel could materially impact our ability to raise capital and ability to secure loans, if needed, in each case on reasonable terms.

It is currently not possible to predict the duration or severity of the ongoing conflict or its effect on our business, operations and financial conditions. The ongoing conflict is rapidly evolving and developing, and could disrupt our business and operations, interrupt our sources and availability of supply and hamper our ability to raise additional funds or sell our securities, among other possible effects.

Furthermore, prior to the war, the Israeli government was pursuing extensive changes to Israel's judicial system. In response to the foregoing developments, critics voiced concerns that the proposed changes may negatively impact the business environment in Israel. If the Israeli government resume the pursuit of such extensive changes, it may negatively affect our business, financial condition and prospects. Further, in the past, the State of Israel and Israeli companies were subjected to economic boycotts. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business.

***Investors may have difficulties enforcing a U.S. judgment, including judgments based upon the civil liability provisions of the U.S. federal securities laws, against us, or our executive officers and directors or asserting U.S. securities laws claims in Israel.***

We are incorporated in Israel. Most of our current executive officers and directors reside in Israel and most of our assets reside outside of the United States. Therefore, a judgment obtained against us or any of these persons in the United States, including one based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States and may not be enforced by an Israeli court unless certain provisions of Israeli law are satisfied. It may also be difficult to effect service of process on these persons in the United States or to assert U.S. securities law claims in original actions instituted in Israel.

Under Israeli law, if U.S. law is found to be applicable to such a claim, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would be governed by Israeli law. There is little binding case law in Israel addressing these matters.

***Under applicable U.S. and Israeli law, we may not be able to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees. In addition, employees may be entitled to seek compensation for their inventions irrespective of their agreements with us, which in turn could impact our future profitability.***

We generally enter into non-competition agreements with our employees and key consultants. These agreements prohibit our employees and key consultants, if they cease working for us, from competing directly with us or working for our competitors or clients for a limited period of time. We may be unable to enforce these agreements under the laws of the jurisdictions in which our employees work and it may be difficult for us to restrict our competitors from benefitting from the expertise our former employees or consultants developed while working for us. For example, Israeli courts have required employers seeking to enforce non-compete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer which have been recognized by the courts, such as the secrecy of a company's confidential commercial information or the protection of its intellectual property. If we cannot demonstrate that such interests will be harmed, we may be unable to prevent our competitors from benefiting from the expertise of our former employees or consultants and our ability to remain competitive may be diminished.

***Your rights and responsibilities as our shareholder will be governed by Israeli law, which may differ in some respects from the rights and responsibilities of shareholders of U.S. corporations.***

Since we are incorporated under Israeli law, the rights and responsibilities of our shareholders are governed by our articles of association and Israeli law. These rights and responsibilities differ in some respects from the rights and responsibilities of shareholders of U.S.-based corporations. In particular, a shareholder of an Israeli company, such as us, has a duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards us and other shareholders and to refrain from abusing its power in us, including, among other things, in voting at the general meeting of shareholders on certain matters, such as an amendment to our articles of association, an increase of our

authorized share capital, a merger and approval of related party transactions that require shareholder approval. A shareholder also has a general duty to refrain from discriminating against other shareholders. In addition, a controlling shareholder or a shareholder who knows that it possesses the power to determine the outcome of a shareholders vote or to appoint or prevent the appointment of an office holder of ours or other power towards us has a duty to act in fairness towards us. However, Israeli law does not define the substance of this duty of fairness. Since Israeli corporate law underwent extensive revisions approximately 15 years ago, the parameters and implications of the provisions that govern shareholder behavior have not been clearly determined. These provisions may be interpreted to impose additional obligations and liabilities on our shareholders that are not typically imposed on shareholders of U.S. corporations.

***Changes in Israeli tax laws and examinations by the Israeli Tax Authorities could increase our overall tax liabilities.***

We are subject to various taxes and tax compliance obligations in Israel. Changes in Israeli tax laws and regulations or their implementation in the future could increase our tax liabilities and our tax compliance obligations. In addition, the proper application of Israeli tax laws is subject to certain uncertainties and require the exercise of judgement. We may be subject to examinations by the Israeli Tax Authorities, and if our application or interpretation of Israeli tax laws is successfully challenged, we could be subject to additional tax liabilities, including interest and penalties, which could adversely affect our business and financial position.

***Provisions of Israeli law may delay, prevent or otherwise impede a merger with, or an acquisition of, our company, which could prevent a change of control, even when the terms of such a transaction are favorable to us and our shareholders.***

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to these types of transactions. For example, a merger may not be consummated unless at least 50 days have passed from the date that a merger proposal was filed by each merging company with the Israel Registrar of Companies and at least 30 days from the date that the shareholders of both merging companies approved the merger. In addition, the holder of a majority of each class of securities of the target company must approve a merger. Moreover, a full tender offer can only be completed if the acquirer receives at least 95% of the issued share capital (provided that a majority of the offerees that do not have a personal interest in such tender offer shall have approved the tender offer, except that if the total votes to reject the tender offer represent less than 2% of the company's issued and outstanding share capital, in the aggregate, approval by a majority of the offerees that do not have a personal interest in such tender offer is not required to complete the tender offer), and the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within six months following the completion of the tender offer, petition the court to alter the consideration for the acquisition (unless the acquirer stipulated in the tender offer that a shareholder that accepts the offer may not seek appraisal rights).

Our articles of association provide that our directors (other than external directors) are elected to terms, with only two or three of our directors (other than external directors) to be elected each year, in each case for a term of three years. The staggering of the terms of our directors prevents a potential acquirer from readily replacing our entire board of directors at a single annual general shareholder meeting. This could prevent an acquirer from seeking to effect a change in control of our company by proposing an acquisition proposal offer opposed by our board, even if beneficial to our shareholders.

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to those of our shareholders whose country of residence does not have a tax treaty with Israel exempting such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as U.S. tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances but makes the deferral contingent on the fulfillment of numerous conditions, including a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are restricted. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no actual disposition of the shares has occurred.

These and other similar provisions could delay, prevent or impede an acquisition of us or our merger with another company, even if such an acquisition or merger would be beneficial to us or to our shareholders.

***Because a certain portion of our expenses is incurred in currencies other than the U.S. Dollar, our results of operations may be harmed by currency fluctuations and inflation.***

Our reporting and functional currency is the U.S. Dollar, but some portion of our operational expenses are in NIS and Euros. As a result, we are exposed to some currency fluctuation risks. We may, in the future, decide to enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rate of the currencies mentioned above in relation to the U.S. Dollar. These measures, however, may not adequately protect us from adverse effects.

**Risks Related to our Securities**

***Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of the ADSs. The delisting could adversely affect the market liquidity of our shares and the market price of our shares could decrease significantly.***

If we fail to satisfy Nasdaq's continued listing requirements, Nasdaq may take steps to delist the ADSs.

On November 1, 2023, we received a notice of non-compliance from Nasdaq that we are not in compliance with the requirement to maintain a minimum bid price of $1.00 per share as required by Nasdaq Listing Rule 5550(a)(2) (the "Rule"). We were given 180 days to regain compliance. On April 30, 2024, we received a staff determination letter from Nasdaq notifying us that, due to our continued non-compliance with the minimum $1.00 bid price requirement, our ADSs would be scheduled for delisting from Nasdaq and would be suspended for trading at the opening of business on May 7, 2024 unless we timely request a hearing before an independent Nasdaq Hearings Panel (the "Hearing Panel"). We have appealed the delisting determination and requested a hearing before the Panel, which automatically stays any suspension. Our board of directors also approved a ratio change of the ADSs to our non-traded ordinary shares, increasing the number of ordinary shares represented by each ADS from 400 to 4,000, which is equivalent to a reverse split of 1 for 10. The anticipated effective date of the ratio change is May 21, 2024. We expect that the ratio change will correct the ADS trading price noncompliance issue, which in turn, because corrected prior to the hearing, would make the need for a hearing moot. If the ratio change does not correct the non-compliance prior to the hearing, we will request an extension of time sufficient to regain compliance vis-à-vis the referenced ratio change or, if necessary, a further ratio change. However, in such a case, there can be no assurance that we will obtain an extension period from the Panel to regain compliance, or, if the Panel grants such an extension period, that we will be able to evidence compliance with the Rule before the extension period expires.

In addition, we received notification letters from Nasdaq dated September 28, 2022 and May 1, 2023 advising us that we are not in compliance with Listing Rule 5550(b)(1) requiring companies listed on Nasdaq to maintain a minimum of $2,500,000 in stockholders' equity for continued listing. On August 1, 2023, we announced that Nasdaq reviewed our plan to regain compliance with Nasdaq's Listing Rule 5550(b) and provided us with an extension until October 30, 2023 to demonstrate compliance. On November 20, 2023, we announced the receipt of formal notification from Nasdaq that we had regained compliance with Nasdaq listing rules regarding minimum stockholders' equity. Nasdaq also indicated that if we do not evidence such compliance in our next periodic report (this Annual Report), Nasdaq may provide notification to us that our ADSs may be subject to delisting, at which time we may appeal the determination to a Hearings Panel. [Our shareholders' equity as of December 31, 2023 as reflected in our financial statements for the year ended December 31, 2023 was less than the minimum of $2,500,000 in stockholders' equity required by Nasdaq for continued listing, and so there is a risk that the ADSs will be delisted from Nasdaq.]

In addition, .

If the ADSs are delisted from Nasdaq, trading of our securities would most likely take place in an over-the-counter market for unlisted securities. An investor would likely find it less convenient to sell, or to obtain accurate quotations in seeking to buy, our securities in an over-the-counter market, and many

investors would likely not buy or sell our securities due to difficulty in accessing over-the-counter markets, policies preventing them from trading in securities not listed on a national exchange or other reasons. In addition, as a delisted security, our securities would be subject to SEC rules as a "penny stock," which impose additional disclosure requirements on broker-dealers. The regulations relating to penny stocks, coupled with the typically higher cost per trade to the investor of penny stocks due to factors such as broker commissions generally representing a higher percentage of the price of a penny stock than of a higher-priced stock, would further limit the ability of investors to trade in our securities. For these reasons and others, delisting would adversely affect the liquidity, trading volume and price of our securities, causing the value of an investment in us to decrease and having an adverse effect on our business, financial condition and results of operations, including our ability to attract and retain qualified employees and raise capital.

A delisting from Nasdaq would likely have a negative effect on the price of the ADSs and would impair shareholders' ability to sell or purchase their ADSs when they wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow the ADSs to become listed again, stabilize the market price or improve the liquidity of the ADSs, prevent the ADSs from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

***U.S. holders of ADSs may suffer adverse tax consequences if we were characterized as a passive foreign investment company.***

Based on the current composition of our gross income and assets and on reasonable assumptions and projections, we believe we should not be treated as a passive foreign investment company (a "PFIC"), for U.S. federal income tax purposes for 2023. However, there can be no assurance that this will be the case in 2023 or in future taxable years. If we were characterized as a PFIC, U.S. holders of the ADSs may suffer adverse tax consequences such as (i) having gains realized on the sale of the ADSs treated as ordinary income rather than capital gain, not qualifying for the preferential rate otherwise applicable to dividends received in respect of the ADSs by individuals who are U.S. holders, and (ii) having interest charges apply to certain distributions by us and upon certain sales of the ADSs.

***We are a "foreign private issuer" and have disclosure obligations that are different from those of U.S. domestic reporting companies.***

We are a foreign private issuer and are not subject to the same requirements that are imposed upon U.S. domestic issuers by the SEC. Under the Exchange Act, we are subject to reporting obligations that, in certain respects, are less detailed and less frequent than those of U.S. domestic reporting companies. For example, we are not required to issue quarterly reports or proxy statements that comply with the requirements applicable to U.S. domestic reporting companies. Furthermore, although under the regulations promulgated under the Companies Law, as an Israeli public company listed overseas we will be required to disclose the compensation of our five most highly compensated officers on an individual basis (rather than on an aggregate basis, as was previously permitted for Israeli public companies listed overseas prior to such amendment), this disclosure will not be as extensive as that required of U.S. domestic reporting companies. We also have four months after the end of each fiscal year to file our annual reports with the SEC and are not required to file current reports as frequently or promptly as U.S. domestic reporting companies. Furthermore, our officers, directors and principal shareholders are exempt from the requirements to report short-swing profit recovery contained in Section 16 of the Exchange Act. Also, as a "foreign private issuer," we are also not subject to the requirements of Regulation FD (Fair Disclosure) promulgated under the Exchange Act. These exemptions and leniencies reduce the frequency and scope of information and protections available to you in comparison to those applicable to U.S. domestic reporting companies.

***As a "foreign private issuer," we are permitted, and follow certain home country corporate governance practices instead of otherwise applicable SEC and NASDAQ Capital Market requirements, which may result in less protection than is accorded to investors under rules applicable to domestic U.S. issuers.***

As a "foreign private issuer," we are permitted, and follow certain home country corporate governance practices instead of those otherwise required under the listing rules of the Nasdaq Capital Market for domestic U.S. issuers. For instance, we intend to follow home country practice in Israel with regard to, among other things, board independence requirements, director nomination procedures and

quorum requirements. In addition, we may follow our home country law instead of the listing rules of the Nasdaq Capital Market that require that we obtain shareholder approval for certain dilutive events, such as the establishment or amendment of certain equity based compensation plans, an issuance that will result in a change of control, certain transactions other than a public offering involving issuances of a 20% or greater interest in the Company, and certain acquisitions of the stock or assets of another company. We also intend to follow our home country rules regarding the periodic approval of and changes to the formal charter for our compensation committee instead of the listing rules of the Nasdaq Capital Market. We may in the future elect to follow home country corporate governance practices in Israel with regard to other matters. Following our home country corporate governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on the Nasdaq Capital Market may provide less protection to you than what is accorded to investors under the listing rules of the Nasdaq Capital Market applicable to domestic U.S. issuers.

***We may lose our foreign private issuer status which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting and other expenses.***

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 applicable to U.S. domestic issuers. If in the future we are not a foreign private issuer as of the last day of the second fiscal quarter in any fiscal year, we would be required to comply with all of the periodic disclosure, current reporting requirements and proxy solicitation rules of the Exchange Act applicable to U.S. domestic issuers. In order to maintain our current status as a foreign private issuer, either (a) a majority of our Ordinary Shares must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our managing directors, supervisory directors and executive officers may not be United States citizens or residents, (ii) more than 50% of our assets cannot be located in the United States and (iii) our business must be administered principally outside the United States. If we were to lose this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and stock exchange rules. The regulatory and compliance costs to us if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the costs we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. These rules and regulations could also make it more difficult for us to attract and retain qualified managing directors and supervisory directors.

***We have not paid, and do not currently intend to pay, dividends on the ADSs and, therefore, unless our traded securities appreciate in value, our investors may not benefit from holding our securities.***

We have not paid any cash dividends on the ADSs since inception. We do not anticipate paying any cash dividends on the ADSs in the foreseeable future. Moreover, the Companies Law imposes certain restrictions on our ability to declare and pay dividends. As a result, investors in the ADSs will not be able to benefit from owning these securities unless their market price becomes greater than the price paid by such investors and they are able to sell such securities. We cannot assure you that you will ever be able to resell our securities at a price more than the price paid.

***You may not receive the same distributions or dividends as those we make to the holders of our Ordinary Shares, and, in some limited circumstances, you may not receive dividends or other distributions on our Ordinary Shares and you may not receive any value for them, if it is illegal or impractical to make them available to you.***

The depositary for the ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on Ordinary Shares or other deposited securities underlying the ADSs, after deducting its fees and expenses. You will receive these distributions in proportion to the number of Ordinary Shares the ADSs represent. However, the depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act, but that are not properly registered or distributed under an applicable exemption from registration. In addition, conversion into U.S. dollars from foreign currency that was part of a

dividend made in respect of deposited Ordinary Shares may require the approval or license of, or a filing with, any government or agency thereof, which may be unobtainable. In these cases, the depositary may determine not to distribute such property and hold it as "deposited securities" or may seek to effect a substitute dividend or distribution, including net cash proceeds from the sale of the dividends that the depositary deems an equitable and practicable substitute. We have no obligation to register under U.S. securities laws any ADSs, Ordinary Shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, Ordinary Shares, rights or anything else to holders of ADSs. In addition, the depositary may withhold from such dividends or distributions its fees and an amount on account of taxes or other governmental charges to the extent the depositary believes it is required to make such withholding. This means that you may not receive the same distributions or dividends as those we make to the holders of our Ordinary Shares, and, in some limited circumstances, you may not receive any value for such distributions or dividends if it is illegal or impractical for us to make them available to you. These restrictions may cause a material decline in the value of the ADSs.

***Holders of ADSs must act through the depositary to exercise their rights as our shareholders.***

Holders of the ADSs do not have the same rights of our ordinary shareholders and may only exercise the voting rights with respect to the underlying Ordinary Shares in accordance with the provisions of the deposit agreement for the ADSs. Under Israeli law, the minimum notice period required to convene a shareholders meeting is no less than 35 or 21 calendar days, depending on the proposals on the agenda for the shareholders meeting. When a shareholder meeting is convened, holders of the ADSs may not receive sufficient notice of a shareholders' meeting to permit them to withdraw their Ordinary Shares to allow them to cast their vote with respect to any specific matter. In addition, the depositary and its agents may not be able to send voting instructions to holders of the ADSs or carry out their voting instructions in a timely manner. We will make all reasonable efforts to cause the depositary to extend voting rights to holders of the ADSs in a timely manner, but we cannot assure holders that they will receive the voting materials in time to ensure that they can instruct the depositary to vote their ADSs. Furthermore, the depositary and its agents will not be responsible for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of the ADSs may not be able to exercise their right to vote and they may lack recourse if their ADSs are not voted as they requested. In addition, in the capacity as a holder of ADSs, they will not be able to call a shareholders' meeting.

***You may be subject to limitations on transfer of the ADSs.***

The ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason in accordance with the terms of the deposit agreement.

***General Risks***

***We incur significant costs as a public company in the United States, and our management is required to devote substantial additional time to new compliance initiatives as well as to compliance with ongoing U.S. and Israeli reporting requirements.***

We are a publicly traded company in the U.S. As a public company in the U.S., we incur additional significant accounting, legal and other expenses. We also incur costs associated with corporate governance requirements of the SEC and the NASDAQ Capital Market, as well as requirements under Section 404 and other provisions of the Sarbanes-Oxley Act. The implementation and testing of such processes and systems may require us to hire outside consultants and incur other significant costs. Any future changes in the laws and regulations affecting public companies in the United States, including Section 404 and other provisions of the Sarbanes-Oxley Act, and the rules and regulations adopted by the SEC and the NASDAQ Capital Market, for so long as they apply to us, will result in increased costs to us as we respond to such changes. These laws, rules and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance,

and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, if any, or as executive officers.

***The market price for the ADSs has been and will likely remain volatile.***

The market price for the ADSs has been and is likely to remain highly volatile and subject to wide fluctuations in response to numerous factors including the following:

- our failure to obtain the authorizations necessary to commence future clinical trials;
- results of clinical and preclinical studies;
- announcements of regulatory approval or the failure to obtain it, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- announcements of technological innovations, new product candidate(s) or product enhancements by us or others;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws, regulations, or decisions applicable to our product candidate(s) or patents;
- any adverse changes to our relationship with manufacturers or suppliers;
- announcements concerning our competitors or the pharmaceutical or biotechnology industries in general;
- achievement of expected product sales and profitability or our failure to meet expectations;
- our commencement of or results of, or involvement in, litigation, including, but not limited to, any product liability actions or intellectual property infringement actions;
- any major changes in our board of directors, management or other key personnel;
- legislation in the United States, Europe and other foreign countries relating to the sale or pricing of pharmaceuticals;
- announcements by us of entering into or termination of significant strategic partnerships, out-licensing, in-licensing, joint ventures, acquisitions or capital commitments;
- expiration or terminations of licenses, research contracts or other collaboration agreements;
- public concern as to the safety of therapeutics we, our licensees or others develop;
- success of research and development projects;
- developments concerning intellectual property rights or regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if the ADSs are covered by these analysts;
- future issuances of Ordinary Shares, ADSs or other securities;

- general market conditions, including the volatility of market prices for shares of biotechnology companies generally, and other factors, including factors unrelated to our operating performance;

- nationalization of vaccines as part of a pandemic due to as part of national security, for example, under the U.S., Defense Production Act seizure of manufacturing; and

- the other factors described in this "Risk Factors" section.

These factors and any corresponding price fluctuations may materially and adversely affect the market price of the ADSs, which would result in substantial losses by our investors.

Additionally, market prices for securities of biotechnology and pharmaceutical companies historically have been very volatile. The market for these securities has from time to time, experienced significant price and volume fluctuations for reasons unrelated to the operating performance of any one company. In the past, the COVID-19 pandemic resulted in significant financial market volatility and uncertainty. A resurgence of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, on our business, results of operations and financial condition, and on the market price of the ADSs.

In the past, securities class action litigation has often been brought against a company and its management following a decline in the market price of its securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant share price volatility in recent years.

In addition, the trading prices for securities of other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. The extent to which the outbreak may impact our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

In addition, the securities market has from time to time experienced significant price and volume fluctuations that are not related to the operating performance of any particular company. These market fluctuations may also have a material adverse effect on the market price of the ADSs.

***Substantial future sales or perceived potential sales of the ADSs in the public market, including ADSs issuable upon exercise of outstanding warrants, could cause the price of the ADSs to decline.***

Substantial sales of the ADSs on Nasdaq may cause the market price of the ADSs to decline. Sales by us or our security holders of substantial amounts of the ADSs, or the perception that these sales may occur in the future, including ADSs issuable upon exercise of outstanding warrants, could cause a reduction in the market price of the ADSs.

The issuance by the Company of any additional ADSs or grant of any securities by the Company that are exercisable for or convertible into our Ordinary Shares or ADSs, may have an adverse effect on the market price of the ADSs and will have a dilutive effect on our existing shareholders and holders of ADSs.

***Your percentage ownership in us may be diluted by future issuances of share capital, which could reduce your influence over matters on which shareholders vote.***

Our board of directors has the authority, in most cases without action or vote of our shareholders, to issue all or any part of our authorized but unissued shares, including Ordinary Shares and ADSs issuable upon the exercise of outstanding options. Issuances of additional shares and ADSs would reduce your influence over matters on which our shareholders vote.

***If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they adversely change their recommendations or publish negative reports regarding our business or our traded securities, the market price for the ADSs and trading volume could be negatively impacted.***

The trading market for our securities may be influenced by the research and reports that industry or securities analysts publish about us, our business, our market or our competitors. We do not have any control over these analysts, and we cannot provide any assurance that analysts will cover us or provide favorable coverage. If any of the analysts who may cover us adversely change their recommendation regarding the ADSs, or provide more favorable relative recommendations about our competitors, the price of the ADSs would likely decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could negatively impact the price of the ADSs or their trading volume.

## Item 4. INFORMATION ON THE COMPANY

### A. History and Development of the Company

**Our History**

Our legal and commercial name is Scinai Immunotherapeutics Ltd. We are a company limited by shares organized under the laws of Israel. We were incorporated in Israel in 2003 as a privately held company. In February 2007, we completed an initial public offering of our ordinary shares on the Tel Aviv Stock Exchange (TASE), and we voluntarily delisted from the TASE in January 2018. In May 2015 we completed an initial public offering of ADSs and ADSs warrants (which have since expired) on the Nasdaq Capital Market. On September 6, 2023, we announced the change of our corporate name to Scinai Immunotherapeutics Ltd. from BiondVax Pharmaceuticals Ltd. to reflect better our fresh start and new direction.

Our principal executive offices are located at Jerusalem BioPark, 2nd floor, Hadassah Ein Kerem Campus, Jerusalem, Israel, and our telephone number is +972-8-930-2529. Our website is www.scinai.com. The information we post on our website may be deemed material. Accordingly, investors should monitor our website, in addition to following our press releases, SEC filings and public conference calls and webcasts. However, the information contained on, or accessible through, our website is not incorporated by reference herein and shall not be considered part of this annual report. Our agent for service of process in the United States is Puglisi & Associates, whose address is 850 Library Avenue, Suite 204, Newark, Delaware, and whose telephone number is (302) 738-6680.

Our capital expenditures for 2023, 2022 and 2021 amounted to approximately $637, $836, and $138 thousand, respectively. These expenditures were primarily for factory leasehold improvements, computers and laboratory equipment.

### B. Business Overview

We are a biopharmaceutical company with two complementary business units, one focused on in-house development of inflammation and immunology (I&I) biological therapeutic products beginning with an innovative, de-risked, pipeline of nanosized VHH antibodies (NanoAbs) targeting diseases with large unmet medical needs, and the other a boutique CDMO providing services to help biotech companies efficiently bring their products to market by leveraging Scinai's drug development and GMP and non-GMP manufacturing capabilities for pre-clinical and clinical studies. .

*Development of I&I biological therapeutic products*

Since inception, we have executed eight clinical trials including a seven country, 12,400 participant phase 3 trial of our prior lead drug candidate, a universal influenza vaccine candidate ("M-001") and have built a GMP biologics manufacturing facility for biopharmaceutical products. After receiving the phase 3 trial results in Q42020, indicating that M-001 did not meet its clinical endpoints, we performed a turnaround process that included raising fresh capital, hiring new talent (including a new CEO), signing a research collaboration agreement with and in-licensing new intellectual property from world leading academic research institutes. Since then, we are in the process of developing a pipeline of diversified and commercially viable products built around innovative nanosized antibodies (NanoAb). NanoAbs are nanosized antibody fragments derived from camelid animals and are also known as VHH-antibodies or Nanobodies. "Nanobody" is a trademark registered by ABLYNX N.V., a wholly owned subsidiary of Sanofi. SCINAI has no affiliation with and is not endorsed by Sanofi.

As part of the abovementioned turnaround, on December 22, 2021, the Company signed a definitive exclusive, worldwide, License Agreement ("LA") with the Max Planck Society ("MPG"), the parent organization of the Max Planck Institute for Multidisciplinary Sciences ("MPI"), and the University Medical Center Göttingen ("UMG"), both in Gottingen, Germany, for the development and commercialization of innovative NanoAbs for the treatment of COVID-19. The agreement provides for an upfront payment, development and sales milestones and royalties based on sales and sharing of sublicense revenues. In addition, the Company signed an accompanying Research Collaboration Agreement ("aRCA") with MPG and UMG in support of the abovementioned development of a COVID-19 NanoAb by MPI and UMG. The aRCA provided for monthly payments to MPG and UMG and had a term until the earlier of two years or the date the Company enters into first in-human clinical trials with the COVID-19 NanoAb. Consequently with our decision to put the COVID19 |Nanoab for partnering, we have agreed with MPG/UMG to stop the aRCA.

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On March 23, 2022, we signed a five-year Research Collaboration Agreement ("RCA"; collectively, with the LA and aRCA, the "MPG/UMG Agreements") with MPG and UMG covering the discovery, selection and characterization of NanoAbs for up to nine molecular targets that have the potential to be further developed into drug candidates for the treatment of disease indications such as psoriasis, psoriatic arthritis, asthma and wet macular degeneration. These are all large and growing markets with underserved medical needs. In each case, the molecular target has been validated as an appropriate target for therapeutic intervention through inhibition by an antibody, thereby significantly reducing the discovery work that typically entails many years of research, high cost and high risk of failure. We believe that we can leverage our NanoAbs' unique and strong binding affinity, stability at high temperatures, and potential for more effective and convenient routes of administration towards competitive commercial viability. We believe that since these are clinical validated targets, we can develop NanoAb treatments with reduced risk and cost and accelerate the time from NanoAb selection to initiation of clinical development. Each NanoAb candidate is therefore positioned as a "biobetter" piggybacking on prior discoveries of others to mitigate risk but with significant potential advantages over existing therapeutics. In addition, while each NanoAb constitutes a novel molecule for which we file patent applications thereby creating a proprietary position, all of the developed NanoAbs when viewed together constitute a pipeline that is built around the same drug discovery, development and manufacturing platform allowing us to reduce risks and save costs. SCINAI has the exclusive option for an exclusive, pre-negotiated worldwide license agreement for the development and commercialization of each of the NanoAbs covered by the RCA with MPG and UMG.

On June 5, 2023, we announced that as part of our ongoing broad-based collaboration with the Max Planck Society and the University Medical Center Gottingen (UMG), we signed an exclusive worldwide license agreement to develop and commercialize VHH antibodies (NanoAbs) targeting Interleukin-17 (IL-17) as treatments for all potential indications, starting with psoriasis and psoriatic arthritis.

In June 2023, we disclosed that we were pursuing a strategic partnership for our COVID-19 self-administered inhaled NanoAb therapeutic/prophylactic which demonstrated highly promising in vivo results in animals and that we will focus on developing the anti-IL-17 NanoAb.

*CDMO services*

On September 6, 2023, we announced the launch of a new business unit named Scinai Bioservices to serve as a CDMO offering a multitude of services to support biotech companies through process development, as well as GMP manufacturing for clinical supplies. We seek to provide high quality, yet affordable CDMO services to accelerate the drug development processes of small biotech companies, including cGMP aseptic processing required for manufacturing of clinical batches.

Our biological drug development and manufacturing services for early-stage pre-clinical and clinical programs of protein-based biological drugs includes highly advanced laboratories and a cGMP pilot plant (designed to meet EMA and FDA regulatory requirements) , upstream and downstream process development, process optimization and scaleup, cGMP manufacturing, Fill & Finish operations (F&F), analytical method development and quality control under GLP conditions supported by a robust quality management system . The manufacturing facility features modular, single-use infrastructure, which enables us to adapt the facility to various manufacturing platforms (such as, for example, fermenters or bioreactors).

We perform our CDMO services at our approximately 1,850 square meters (20,000 square feet) facility which we lease in the Jerusalem BioPark, located in the Ein Kerem Hadassah campus, next to Hadassah University Hospital and the Hebrew University's Medical School.

***Our Competitive Strengths***

We believe that our people, processes and technologies give us distinct advantages over our competitors, as follows:

- **People**: Our leadership team has deep biotech and pharmaceutical industry experience, including our Chairman of the Board Mark Germain (former Co-Chairman of Pluri (previously Pluristem Therapeutics), and a co-founder and former director of a number of other biotechnology companies including, without limitation, Alexion, Neurocrine, ChromaDex Inc., Stem Cell Innovations Inc., Omnimmune Corp. and Collexis Holdings Inc.), Board director Samuel Moed (former Senior VP Corporate Strategy at Bristol Myers Squibb), Board director Jay Green (former Senior VP Finance and CFO of GSK's global vaccines business) and COO Elad Mark (formerly employed by Novartis). Our CEO, Amir Reichman, has extensive vaccines R&D, supply chain, manufacturing, and engineering experience from Novartis in the U.S. and GSK in Europe. Furthermore, our Chief Science Officer, Dr. Tamar Ben-Yedidia, oversaw M-001 vaccine development from early research at the Weizmann Institute through the pivotal Phase 3 clinical trial. Dr. Ben-Yedidia conducted her preliminary research in the 1990's under the guidance of Professor Ruth Arnon. Professor Arnon continues to serve as head of Scinai's Scientific Advisory Board.

- **Processes**: After years of experience, Sinai has developed a mature set of business processes including pre-clinical and clinical development, regulatory, quality and GMP manufacturing processes. These processes can help us accelerate time to market for future in-licensed assets and hence provide us with a competitive advantage versus other companies of our size. In the past, we conducted a pivotal Phase 3 trial in over 100 clinical trial sites in seven Eastern European countries, subject to, among others, the regulation of the European Medicines Agency (EMA). The trial was completed on time and on budget. Our Phase 3 clinical trial was initiated after we completed two Phase 1/2 clinical trials and three Phase 2 clinical trials in Israel pursuant to clinical trial protocols approved by the Israeli Ministry of Health, a Phase 2b clinical trial in Europe, and a Phase 2 clinical trial sponsored and conducted by the NIH/NIAID in the USA.

- **Technology**: Our existing and advanced GMP manufacturing facility in Jerusalem uses an agile and modular 'Single Use' infrastructure that can be used for a wide variety of applications and technologies, such as the production of recombinant proteins, nanobodies and other vaccines and treatments. In addition, we have advanced automation, data management and IT systems necessary for regulatory compliant clinical development, clinical supplies and commercial supplies.

***Our Business Strategy***

Beginning with the MPG/UMG Agreements, the Company intends to implement a strategy that will build a diversified pipeline of assets along several axes, as follows:

- A pipeline of products for prevention and/or treatment of illnesses with large market opportunities for more effective treatments.

- Each product candidate originated through the MPG/UMG Agreements would be designed to interact with target previously validated as an appropriate target for therapeutic intervention by an antibody already on the market.

- Each therapeutic indication nevertheless is underserved by existing antibody treatments and a large market opportunity exists for a proprietary NanoAb with improved attributes.

- A pipeline that would take advantage of the unique physicochemical attributes of our NanoAbs, including:

    - Nano size and physical stability – our NanoAbs are approximately 1/10th the size of regular antibodies and have a durable molecular structure. This allows them to be delivered through routes of administration (e.g., intra-dermal, nasal, inhalation, etc.) not particularly amenable to regular antibodies, which are too large and/or easily break down under pressure, opening new or enlarged market opportunities for our NanoAbs.

    - Ultra-high thermo-stability – our NanoAbs retain biological activity even at high temperatures. This provides extended shelf life and may reduce the need for cold chain shipping and storage.

    - Extremely high binding affinity to the target with effective neutralization. Binding affinity is the likelihood that a drug molecule (e.g., a single NanoAb) will find, and attach to its designated target thereby contributing to therapeutically relevant neutralization of the target. This could translate to faster onset of medical efficacy or in some cases it may translate to lower required human dosage compared to other antibodies. That said, this should be demonstrated in clinical trials.

    - High specificity - Our NanoAbs have high specificity to their intended target, and therefore fewer of them are expected to bind to targets other than the designated target, resulting in fewer side effects. Furthermore, and because of their relatively short half-life, any NanoAbs, that do not bind to a target are expected to be quickly degraded or excreted from the body, thus also limiting future adverse effects.

- A pipeline of products that can progress through the discovery stage and enter the clinic relatively quickly compared to traditional monoclonal antibody drug discovery.

    - Traditional monoclonal antibody drug discovery entails years of research identifying and validating a target, identifying the appropriate type of molecule to interact with that target, validating that the mechanism of action can produce a therapeutically relevant benefit with a satisfactory safety profile and that the drug can be produced at an acceptable cost of goods.

    - Together with an international management consulting firm, we have triaged through more than 800 potential molecular targets for our NanoAbs and selected those that had already been validated as targets for commercially available monoclonal antibodies. Furthermore, we filtered for targets for disease treatments that still leave a large unmet need or a large, underserved patient population. We then selected those targets that we believe have the highest commercial value but lowest clinical development costs (small sized clinical trials with fastest timeline to in human proof of concept).

    - Our collaborators at MPG/UMG have been able to generate large libraries of NanoAbs against most of our pre-validated targets within the first 12 months of the collaboration and in many cases have selected from those libraries a small portfolio of candidates that meet or are close to meeting a set of pre-agreed Compound Acceptance Criteria, which we have agreed make them potentially appropriate for further development.

    - As a consequence, over the next 12 to 24 months, subject to having sufficient capital, we believe we will be in a position to execute our exclusive option for exclusive license for development and commercialization of several of the abovementioned nanoAbs and advance them, in addition to our COVID-19 and IL-17 NanoAbs, through remaining pre-clinical development and, subject to available capital resources, updated analysis of market opportunities, partner interest and other relevant factors determined at the time, potentially initiate first in human clinical trials, all in a time frame we believe to be much quicker, at

a cost much lower, and with fewer unknowns/less risk than traditional monoclonal antibodies drug discovery at the same stage of development.

- A pipeline of products that can be developed through the various Chemistry, Manufacturing and Controls steps (CMC) and then be produced for clinical development and potentially initial commercial volumes required for product launch at a low cost of goods at our existing manufacturing facility in Jerusalem, built to GMP standards.

    - Our NanoAbs are produced in yeast, a relatively low cost and rapid production system compared to the manufacture of regular antibodies. Regular antibodies are produced in mammalian cell lines that take considerable time to establish, require a much more sophisticated production facility, have lower yields and involve more expensive processing to harvest and purify the ultimate drug substance.

    - Our facility in Jerusalem is equipped to take the candidates generated by MPG/UMG and immediately begin development of NanoAbs for pre-clinical testing and ultimately produce clinical grade NanoAbs.

    - By conducting these activities in-house, we will be in a position to avoid the delays and high costs typically associated with third party contract manufacturers and have more direct control over the process.

If successfully implemented, this strategy would provide Scinai with a diverse multi-dimensional pipeline that we believe has been substantially de-risked without necessarily limiting the upside potential. We would also expect to have considerable flexibility regarding partnering with other companies in the pharmaceutical industry, out-licensing, joint ventures and the like. The Company is currently actively engaged in identifying and evaluating many of these opportunities. Notwithstanding the Company's efforts to mitigate the risk associated with the development of our NanoAbs, there remains significant risk of failure, as described under "Risks Related to Our Business", associated with product development, manufacturing, regulatory matters, capital availability, commercialization, and other factors relevant to small companies, such as Scinai, engaged in early stage pharmaceutical development activities.

**Research and Development**

On September 20, 2022, we announced that MPG and UMG have successfully generated, identified and isolated NanoAbs addressing a number of additional biological target molecules as specified in the RCA. Based on these promising results, the Scinai-MPG-UMG Joint Steering Committee, established to guide the RCA programs, decided to focus further development beginning with the following NanoAbs, targeting immune system cytokines:

- NanoAbs targeting IL-17A, IL-17F and IL-17A/F complex as drug candidates for the potential treatment of psoriasis and psoriatic arthritis.

- NanoAbs targeting IL-13 and NanoAbs targeting TSLP as drug candidates for the potential treatment of asthma.

As mentioned above, on June 5, 2023, we signed an exclusive worldwide license agreement to develop and commercialize VHH antibodies (NanoAbs) targeting Interleukin-17 (IL-17) as treatments for all potential indications, starting with psoriasis and psoriatic arthritis. In addition, as disclosed under "Business Overview", in June 2023, we disclosed that we were pursuing a strategic partnership for our COVID-19 NanoAb and that we will focus on developing the anti-IL-17 NanoAb.

P*re-Clinical Trial of anti-IL-17 NanoAb mild to moderate plaque psoriasis*

In December 2023, we announced successful preclinical trial results of the anti-IL-17 NanoAb, as a local treatment for the large and underserved population of mild to moderate plaque psoriasis. The study, conducted by Genoskin (FR), a pioneering French biotechnology company, aimed to evaluate the

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anti-inflammatory effects of our NanoAbs. Genoskin's proprietary human skin models were induced for expression of plaque psoriasis symptoms to enable ex-vivo examination of the therapeutic effects of drugs targeting underlying mechanisms in the pathogenesis of plaque psoriasis, particularly the IL-17 family of pro-inflammatory cytokines. This disease-induced skin model reproduces key features of plaque psoriasis tissue morphology as well as the cytokine profile associated with the inflammatory state of plaque psoriasis lesions. Genoskin's model has been successfully validated[1] as a reliable ex-vivo system for testing drugs aimed at plaque psoriasis.

The trial's study groups included intradermal injections in two dosage schedules of our anti-IL-17 NanoAbs, which were compared to Cosentyx® (a leading monoclonal anti-IL-17A antibody treatment for severe psoriasis), Betamethasone (a topically applied corticosteroid used a treatment for mild to moderate psoriasis), an unrelated VHH NanoAb, and an untreated control. The anti-inflammatory effect of our NanoAbs were evaluated by measuring cytokine levels secreted by the skin tissues, including IL-17 family cytokines. Additionally, the skin's structure, integrity, and viability were assessed by a histological analysis.

The statistically significant results demonstrated the potential for our anti-IL-17 NanoAbs to noticeably improve psoriatic skin lesions as indicated by skin viability and structural integrity. This finding was corroborated by cytokine release analysis, which showed significantly reduced IL-17 release ($p<0.001$) upon treatment with our IL-17 nanoAb as compared to the untreated control, similar to the effects of Betamethasone and Cosentyx.

The results confirm and build upon previously reported results indicating that our anti-IL-17 NanoAbs downregulated key molecular markers overexpressed in plaque psoriasis in a 3D scaffold of skin cells, a model mimicking a skin tissue. We have recently conducted an in-vivo proof of concept animal study in early 2024 in collaboration with Technion Israel Institute of Technology. Results of this study are expected in June 2024. Upon favorable results from the abovementioned PoC in vivo study we plan to conduct a pre-clinical toxicology study before commencing a first-in-human clinical trial in H2 2025.

*NanoAb program for COVID-19*

Despite encouraging set of in-vitro and in-vivo animal studies showing that inhalation of our COVID-19 NanoAbs has the potential to effectively treat or prevent infection by various strains of COVID-19, we have suspended further development of the COVID-19 NanoAbs program due to changing market conditions for COVID therapeutics and may not continue unless we find a partner to further develop this program.

- Technology transfer of several COVID-19 potential lead drug candidates has been conducted and included manufacturing process development and analytical methods development, and initial manufacturing has been commenced.

- We have partnered with two world-renowned institutes to conduct a preclinical proof-of-concept in vivo study of the COVID-19 NanoAb targeting the Wuhan strain as a proof-of-concept study of a NanoAb as an inhaled therapy in COVID-19 infected animals: The Fraunhofer Institute for Toxicology and Experimental Medicine (ITEM) and The University of Veterinary Medicine Hannover (TiHo), Germany. The trial commenced in Q4 2022 and used an industry-standard animal model that correlates severity of disease with weight loss. The trial we conducted compared weight loss, among other vitality and illness parameters in four groups of hamsters after infection with SARS-COV-2. The experimental groups were treated with our anti-COVID-19 NanoAb, as an inhaled therapy, in descending doses, starting one day after being infected, while the control group was treated in the same manner but with saline serving as a placebo. On November 29, 2022, we reported results from our high dose experimental group in comparison to the control group and showed that, compared to their weight immediately prior to infection, the control group's weight declined on average 12.01%, considered to be indicative of severe disease, while the weight of the high dose experimental group, which was administered by our NanoAb through inhalation, declined on average only 3.80%, a highly statistically significant **result** ($p<0.001$). The successful result was further supported by eight other tracked parameters, including heart rate and social behaviors, that indicated the group

treated with inhaled NanoAbs experienced a milder and shorter illness. The results from the two lower doses of our inhaled anti COVID-19 NanoAb were not different than those demonstrated by the high dose. On January 6, 2023, we announced additional results from the preclinical in vivo proof-of-concept study, namely that six days after infection, compared to the placebo group, hamsters treated with our inhaled NanoAb not only had over 30 times lower SARS-COV-2 viral titers in their lungs as measured by median tissue culture infectious dose (TCID50) but also those levels were at the border of detection, suggesting potential virtual elimination of the virus from their lungs. These results were corroborated also by PCR.

- On January 23, 2023, we announced additional results from the preclinical in vivo proof-of-concept study, this time testing a prophylactic use of our anti-COVID-19 NanoAbs in prevention of COVID-19 disease. The study compared weight loss in two groups of hamsters. Hamsters administered a mid-sized dose of the NanoAb three hours prior to infection experienced no significant weight loss over the six-day trial, whereas the untreated control group's weight declined 12% on average, a highly statistically significant difference ($p<0.0005$). Data from our trial indicate that our NanoAb may effectively serve as both a therapeutic and protective prophylactic drug. A pilot quantity of the NanoAb was manufactured in-house and sent to our consulting partner supporting us with the development of a formulation and selection of an inhalation device for human use.

We received supportive Scientific Advice for our COVID-19 NanoAb development plans from the Paul Ehrlich Institute (PEI), an agency of the German Federal Ministry of Health whose research and control activities promote the quality, efficacy and safety of biological medicinal products. PEI supported our plan for first-in-human clinical trial to be conducted directly in sick patients as a combined Phase 1/2a, testing both safety and efficacy, thereby shortening our potential clinical development timelines.

As mentioned above, as part of the five-year Research Collaboration Agreement, MPI and UMG have been able to discover and characterize additional NanoAbs aimed at molecular targets pre-defined by Scinai with first being an anti-IL-17 NanoAb that is planned for treatment of psoriasis (but not limited to) and for which Scinai obtained an exclusive license as mentioned above. Additional NanoAbs targeting IL-13 and TSLP, which can be used for the treatment, but not limited to, of asthma and Atopic Dermatitis, might reach their acceptance criteria to trigger our exclusive option for exclusive license for development and commercialization worldwide.

**Competition**

Generally, our competitors include large, fully integrated pharmaceutical companies as well as companies and academic research institutes in various developmental stages attempting to develop (i) COVID-19 antibody therapeutics (such as Invivyd (formerly Adagio Therapeutics), Vir Biotechnology, and ExeVir)) as well as (ii) other products for the prevention and treatment of disease targets that are the subject of our broader agreement with MPG and UMG, including MoonLake Immunotherapeutics AG for the development of antibodies against psoriasis.

**Marketing and Sales**

We do not currently have any pharmaceutical product marketing or sales capabilities. We intend to license to, or enter into strategic alliances, with third parties in the pharmaceutical business, which are equipped to market and/or sell any products that we acquire or develop in the future. We may seek to establish such capabilities internally in the future, if and when appropriate, in addition to any such licensing arrangements or strategic alliances.

**Manufacturing**

We built, own, and operate a biologics manufacturing facility in Jerusalem, which is capable of manufacturing GMP-compliant product candidates for use in either clinical trials or for small to medium scale commercial supply. We have manufactured the COVID-19 and IL-17 NanoAbs for our preclinical in vivo studies in our facility, and although we currently anticipate using our facility for future manufacturing of product candidates, we may also rely on a third party CMO.

**Properties**

***Office Leasing Agreement***

We lease approximately 1,850 square meters (20,000 square feet) in the Jerusalem BioPark, located in the Ein Kerem Hadassah campus, next to Hadassah University Hospital and Hebrew University's Medical School. The facility includes laboratories, offices, and upstream and downstream manufacturing suites for bulk production and limited capacity for single-dose syringe filling. We also have infrastructure to support future product manufacturing processes and equipment. The manufacturing facility features modular, single-use infrastructure, which enables us to adapt the facility to various manufacturing platforms (such as, for example, fermenters or bioreactors).

We believe this existing property is sufficient for our needs in the foreseeable future and that we have the ability to renew our lease at market terms and expand if required.

***Fixed Assets***

Our fixed assets are comprised of factory leasehold improvements, laboratory equipment, furniture, software and improvements in the leased property. The accumulated depreciation as stated in our financial reports is deducted from the fixed assets value. Our fixed assets, less deduction for the accumulated depreciation, were $10.8 million for the period ended on December 31, 2023 and $11.2 million for the period ended on December 31, 2022.

***Our Main Laboratory***

Our facility in Jerusalem consists of laboratories, manufacturing suites, and offices. The laboratories include (i) an analytical lab, which conducts quality tests on our products using our designated analytical methods; and (ii) technical research and development lab for manufacturing process development and scale up. The manufacturing suites, defined as "clean rooms", include a fermentation suite ("upstream"), a protein purification suite ("downstream"), a formulation suite, an aseptic, automated pre-filled syringes/vials filling, and an equipment cleaning and sterilization suite. In addition, we have two GMP cold, and ambient temperature storage areas.

Scinai's modern cGMP pharmaceutical manufacturing facility is designed in a modular 'Single Use' technology concept enabling relatively flexible production capabilities. Equipment units are mobile and can be replaced or relocated. The facility includes sufficient room to conduct upstream, downstream and media / buffer preparation processes. Each clean room is segregated with a separate Fan Filter Unit (FFU) designed to avoid cross contamination.

The analytical lab is equipped with advanced equipment and machinery including computerized analytical devices for qualitative and quantitative analysis, equipment for measuring light absorption properties for identifying substances, equipment for measuring weight, acidity and temperature, and equipment for identifying replication of DNA sequences.

Our laboratory also includes a separate technician room which contains our computers and software used to collect the data received from our different devices for the purpose of analyzing it. The lab also contains refrigerators and freezers which are consistently monitored and that are connected to a computerized control system. The production rooms are equipped with a fermentation facility, machinery for filtering and concentrating proteins, a computerized system for the characterization and separation of proteins, as well as equipment allowing us to work under sterile conditions.

The facility also includes a Water for Injection (WFI) water purification system. The WFI system is controlled and monitored continuously.

**Research and other Grants**

***Finance Contract – European Investment Bank***

**Commented [MG20]:** to be updated as necessary to reflect conversion of EIB debt to equity.

We borrowed 24 million Euro under a finance contract (the "Finance Contract") with the European Investment Bank (the "EIB"), to finance a portion of the cost of developing our previous leading drug candidate M-001and our GMP biologics manufacturing facility. As part of the Finance Contract, we also entered into a security agreement (the "Security Agreement"), whereby we created a first ranking floating charge in favor of EIB over substantially all of our assets (other than certain licensed intellectual property related to our former M-001 program).

On August 10, 2022, we announced the successful conclusion of negotiations and formal approval by the EIB of new terms of its outstanding €24 million loan (the "Loan") to Scinai, including:

- **Loan extension:** An extension of the maturity dates from 2023 (€20 million) and 2024 (€4 million) until December 2027.

- **Interest accrual:** Although the Loan has been outstanding since 2018, interest on the Loan will only begin to accrue starting January 1, 2022, at an annual rate of 7%. The interest payments will be deferred until the new maturity date and will be added to the principal balance at the end of each year during the Loan period.

- **Interest repayment:** $900,000 was paid by Scinai shortly after the execution of the relevant amendment letter with the EIB and was applied to reduce the outstanding Loan. An additional approximately $725,000 was paid during February, 2023 in connection with the financing completed in December 2022 and an additional $108,000 was paid during 2023 in connection with the financing completed in September 2023. Going forward 10% of any capital raises until maturity will be used to further repay the Loan Interest including any outstanding accrued interest.

- **Variable remuneration to the EIB:** Once Scinai's commercial sales exceed €5 million, 3% of Scinai's topline revenues will be paid to the EIB as royalties until the EIB receives (from the Loan repayment, *inter alia* the interest and the royalties) the higher of (i) a total of 2.8 times the original €24 million principal (as provided in the original Loan agreement) and (ii) 20% IRR on the principal calculated from January 1, 2022.

- **Prepayment indemnity:** In case Scinai decides to discharge all liabilities under the Finance Contract, *inter alia*, payments of the variable remuneration, Scinai would need to repay to the EIB an indemnity amount in addition to the Loan principal and the accrued interest. The indemnity will be calculated such that the EIB receives an additional payment equal to the greater of (i) the prepayment amount (i.e. twice the prepayment amount in the aggregate) and (ii) the amount required to realize 20% IRR on the prepayment amount at the time of prepayment.

On November 29, 2023, we announced the execution of a formal amendment to our finance contract with the European Investment Bank (EIB). The amendment extended the maturity date of the contract by four years from December 31, 2027 to December 31, 2031.

***Israeli Innovation Authority***

Since 2006, we have owed approximately $6.2 million in grants to the Israeli Innovation Authority (IIA), formerly known as the Office of the Chief Scientist. The grants were for research and development of M-001. In light of the Phase 3 clinical trial results, we do not currently expect any future revenues from M-001 and therefore do not currently expect to make any royalty payments to the IIA. The Company is subject to various other restrictions pursuant to the grants, including limitations on transferring IP developed with grant funds. In light of the Company's new strategy, we do not expect these restrictions to be material to our ongoing operations.

In November 2023, we announced that the IIA had approved a non-dilutive grant, with effective date being September 1 2023, covering 66% of the costs of an NIS 3.5 million (approximately $1.0 million) project aimed at ramping up our new CDMO business unit. The grant is neither subject to repayment nor tied to royalty payments of any kind. The grant covers approved expenses required for further developing Scinai's CDMO service for the 12 months from grant. IIA informed us that in August 2024 Scinai can

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apply for a grant extension covering 66% of additional NIS 1.5 million. We intend to apply for the grant extension option.

**Government Regulation**

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***United States***

*FDA Regulations*

In the United States, the FDA regulates pharmaceuticals and biologics under the Food, Drug & Cosmetics Act, and the Public Health Service Act, and their implementing regulations. These products are also subject to other federal, state, and local statutes and regulations, including federal and state consumer protection laws, laws protecting the privacy of health-related information, and laws prohibiting unfair and deceptive acts and trade practices.

The process required by the FDA before a new drug product may be marketed in the United States generally involves the following: completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations; submission to the FDA of an IND application, which must allow become effective before human clinical trials may begin and must be updated annually; performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication; and submission to the FDA of a "new drug application ("NDA") for a drug, and Biologic License Application (BLA) for biological product, after completion of all pivotal clinical trials.

An IND application, while technically a request for a federal approval to transport or distribute a drug across state lines, is, in effect, a request for authorization from the FDA to administer an investigational drug product to humans. In the future, we may consider submitting an IND application to the FDA for initiating clinical trials or, if required, to conduct a bridging clinical study to allow licensure of a Company product candidate in the U.S.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators in accordance with current Good Clinical Practices, or GCP, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site's IRB, before the trials may be initiated, and the IRB must monitor the trial until completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

Generally, three phases of clinical trials are conducted prior to receiving regulatory marketing approval: Phase 1 clinical trials are normally conducted in small groups of healthy volunteers to assess safety and find the potential dosing range. After a safe dose has been established, the drug is administered to small populations of eligible participants (Phase 2) to look for initial signs of efficacy in treating the targeted disease or condition and to continue to assess safety. In the case of vaccines, the participants are healthy, and the signs of efficacy can be obtained in early Phase 1, therefore this Phase is defined as Phase 1/2. Phase 3 clinical trials are usually multi-center, double-blind controlled trials in hundreds or even thousands of subjects at various sites to assess as fully as possible both the safety and effectiveness of the drug.

The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group reviews unblinded data from clinical trials and provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. We may also suspend or terminate a clinical trial based on evolving business objectives and/or the competitive climate.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational drug product information is submitted to the FDA in

the form of a BLA as compared to an NDA for general traditional small molecule drugs requesting approval to market the product for one or more indications. The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, and controls and proposed labeling, among other things. Given the complexities of manufacturing biological products that are processed from living material, BLA content must also demonstrate purity specifically in terms of showing that the final product does not contain extra material.

Once the BLA submission has been accepted for filing, the FDA's goal is to review applications within 10 months of filing. However, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations.

After the FDA evaluates the BLA and conducts inspections of manufacturing facilities where the drug product will be formulated and where the drug will be produced, it may issue an approval letter or, instead, 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 is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. The FDA could also approve the BLA with a risk evaluation and mitigation strategy to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, participant registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

After regulatory approval of a drug product is obtained, the drug producer is required to comply with a number of post-approval regulations. As a holder of an approved BLA, we would be required to report, among other things, certain adverse reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for any of our products. These promotion and advertising requirements include, among others, standards for direct-to-consumer advertising, prohibitions against promoting drugs for uses in participant populations that are not described in the drug's approved labeling (known as "off-label use"), rules for conducting industry-sponsored scientific and educational activities and other promotional activities, Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses. Failure to comply with FDA requirements can have negative consequences, including the immediate discontinuation of marketing activities and noncomplying materials, adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Such enforcement may also lead to scrutiny and enforcement by other government and regulatory bodies.

Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to ensure and preserve the long-term stability of the drug product. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive, and record keeping requirements. In addition, 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 and documentation 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.

Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our CMOs or licensees that may disrupt production or distribution or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of any Company product candidates we may develop in the future.

The FDA also may require post-marketing testing, or Phase 4 testing, as well as risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could otherwise restrict the distribution or use of the product.

***Expedited Development and Review Programs***

The FDA has a number of programs intended to expedite the development and review of product candidates. For example, Fast Track designation is intended to expedite or facilitate the process for reviewing new biological products that meet certain criteria. Specifically, new biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the 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 new biological product may request the FDA to designate the biological product as a Fast Track product at any time during the clinical development of the product. Unique to a Fast Track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. FDA may revoke the Fast Track designation if it believes that the designation is no longer supported by data emerging in the clinical trial process.

Under the Breakthrough Therapy program, products intended to treat a serious or life-threatening disease or condition may be eligible for Breakthrough Therapy designation, which includes eligibility for the benefits of the Fast Track program, when preliminary clinical evidence demonstrates that such product may have substantial improvement on one or more clinically significant endpoints over existing therapies. Additionally, FDA will seek to ensure the sponsor of a breakthrough therapy product receives timely advice and interactive communications to help the sponsor design and conduct a development program as efficiently as possible.

A product is eligible for priority review if it is intended to treat a serious condition and, if approved or licensed, it would provide a significant improvement in safety or effectiveness. FDA intends to take action on a priority review marketing application within six months of receipt, compared to 10 months of receipt for regular review submissions.

Additionally, a product may be eligible for accelerated approval if it is intended to treat a serious or life-threatening disease or condition and would provide meaningful therapeutic benefit over existing treatments. Accelerated approval may be granted on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality and is reasonably likely to predict an effect on irreversible morbidity, mortality, or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a biological product receiving accelerated approval diligently perform adequate and well-controlled post marketing clinical studies demonstrating clinical benefit. In addition, the FDA requires as a condition for accelerated approval the submission of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, Breakthrough Therapy designation, priority review and accelerated approval do not change the standards for licensure but may expedite the review process.

***Pediatric Studies and Exclusivity***

Under the Pediatric Research Equity Act of 2003, a BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the biological product 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. With enactment of the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, sponsors must also submit pediatric study plans prior to the assessment data.

Those pediatric study plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after licensure of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is a type of non-patent marketing exclusivity in the U.S. and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

***FDA Review of BLAs***

After completion of the required clinical testing, a BLA is prepared and submitted to the FDA. FDA approval of the BLA is required before marketing of the product may begin in the U.S. The BLA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting a BLA is substantial. The submission of most BLAs is additionally subject to a substantial application user fee, currently exceeding $2,875,842 for fiscal year 2021, and the manufacturer and sponsor under an approved BLA are also subject to annual program fees, currently $336,432 for each prescription product. These fees are typically increased annually. Sponsors of applications for drugs granted Orphan Drug Designation are exempt from these user fees.

The FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept a BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of BLAs to encourage timeliness. Applications for standard review drug products are meant to be reviewed within ten months; applications for priority review drugs are meant to be reviewed in six. Priority review can be applied to drugs that the FDA determines offer major advances in treatment or provide a treatment where no adequate therapy exists. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA is required to refer an application for a novel biological product to an advisory committee or explain why such referral was not made. An advisory committee is typically a panel that includes clinicians and other experts—for review, evaluation and a recommendation as to whether the

application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not license the product unless compliance with cGMPs is satisfactory, and the application meets the appropriate standard. A BLA must include data that demonstrate that the biological product is safe, pure, and potent.

After the FDA evaluates the BLA and accompanying information and the manufacturing facilities, it issues either an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

An approval or licensure letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of BLA licensure, the FDA may require a REMS, to help ensure that the benefits of the biological product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals and ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product licensure may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product licenses may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

If the FDA approves a product, it may limit the approved indications for use for the product; require that contraindications, warnings or precautions be included in the product labeling; require that postmarketing studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after licensure; require testing and surveillance programs to monitor the product after commercialization; or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval, as applicable, of a new BLA or supplement before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing supplements as it does in reviewing BLAs.

***Biosimilars and Reference Product Exclusivity***

The BPCIA created an abbreviated approval pathway for biological product candidates shown to be highly similar, or "biosimilar," to or interchangeable with an FDA licensed reference biological product. Biosimilarity, which requires that a product is highly similar to the reference product notwithstanding minor differences in clinically inactive components, and that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can generally be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the interchangeable biosimilar and the reference biological product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product. A product shown to be biosimilar or interchangeable with an FDA-approved reference biological product may rely in part on the FDA's previous determination of safety and effectiveness for the reference product for approval, which can potentially

reduce the cost and time required to obtain approval to market the product. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles and have slowed implementation of the BPCIA by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of reference product exclusivity, another company may obtain FDA licensure and market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A biological product can also obtain pediatric market exclusivity in the U.S. As stated above, 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 study in accordance with an FDA-issued "Written Request" for such a study.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, there has been discussion of whether Congress should reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate implementation of the BPCIA is subject to significant uncertainty.

***Post-Licensure FDA Requirements***

Biological products manufactured or distributed pursuant to FDA licenses are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion with the product. After licensure, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and licensure. There also are continuing annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

Often times, even after a biological product has been licensed by the FDA for sale, the FDA may require that certain post-licensure requirements be satisfied, including the conduct of additional clinical studies. If such post-approval requirements are not satisfied, the FDA may withdraw its licensure of the biological product. In addition, holders of a biological product license are required to report certain adverse reactions to the FDA, comply with certain requirements concerning advertising and promotional labeling for their products, and continue to have quality control and manufacturing procedures conform to cGMP after approval. In addition, biological product manufacturers and their subcontractors are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements and other aspects of regulatory compliance. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Among the conditions for BLA licensure is the requirement that the manufacturing operations conform on an ongoing basis with cGMP. In complying with cGMP, we must expend time, money and effort in the areas of training, production and quality control within our own organization and at our contract manufacturing facilities. A successful inspection of the manufacturing facility by the FDA is usually a prerequisite for final licensure of a biological product. Following licensure of the BLA, we and

our manufacturers will remain subject to periodic inspections by the FDA to assess continued compliance with cGMP requirements and the conditions of licensure. We will also face similar inspections coordinated by foreign regulatory authorities. The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing facilities; this latter effort includes assessment of compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

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

- restrictions on the marketing or manufacturing of the product, including total or partial suspension of production, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-licensure clinical trials;
- refusal of the FDA to license pending BLAs or supplements, or suspension or revocation of product licensure;
- 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 the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates marketing, labeling, advertising and promotion of products that are placed on the market. Biological products may be promoted only for the licensed indications and in accordance with the provisions of the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability. 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 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. Such off-label uses are common across medical specialties. 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.

In addition, the distribution of prescription drug products, including most biological products that require a prescription, is subject to the Prescription Drug Marketing Act, or the PDMA, which regulates the distribution of 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 drug product samples and impose requirements to ensure accountability in distribution.

*Other U.S. Healthcare Laws and Compliance Requirements*

Among others, the FDA, HHS, Office of Inspector General, the CMS and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the preclinical and clinical development, manufacture, marketing, and distribution of drugs such as those we are developing. These agencies and other federal, state, and local entities regulate, among other activities, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, sales, commercialization, marketing, advertising and promotion, distribution, post-approval monitoring and reporting, sampling, and export and import of our product candidates. Any drug candidates that we develop must be approved by the FDA before they may be legally marketed in the U.S. 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 U.S., although there can be important differences. Additionally, some significant aspects of regulation in the EU are addressed in a centralized way, but country-specific regulation remains essential in many respects.

Although we do not currently have any products on the market, in addition to FDA restrictions on marketing of pharmaceutical products, we are also subject to healthcare statutory and regulatory requirements and enforcement by the U.S. federal and state governments. Pharmaceutical companies like us 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. Such regulation and may constrain the financial arrangements and relationships through which we research, develop, and, ultimately, sell, market, and distribute any products for which we obtain marketing approval. Such laws include, without limitation:

- The federal Anti-Kickback Statute, an intent-based criminal statute that prohibits, among other activities, persons and entities from knowingly and willfully soliciting, offering, paying, receiving, or providing any remuneration (including any kickback, bride, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, any item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as Medicare or 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 federal civil and criminal false claims laws, including the civil FCA, which prohibit individuals or entities from, among other activities, knowingly presenting, or causing to be presented, to the federal government claims for payment or approval that are false, fictitious, or fraudulent; knowingly making, using, or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. In addition, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as a "whistleblower" to bring *qui tam* actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery or settlement.

- The federal civil monetary penalties laws, which prohibit, among other activities (1) arranging for or contracting with an individual or entity that is excluded from participation in federal healthcare programs to provide items or services reimbursable by a federal healthcare program, (2) failing to report and return a known overpayment, or (3) offering or transferring any remuneration to a Medicare or Medicaid beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of items or services reimbursable by Medicare or Medicaid, unless an exception applies.

- The federal criminal statutes enacted under HIPAA which impose criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property

owned by, or under the custody or control of, any healthcare benefit program; knowingly and willfully embezzling or stealing from a healthcare benefit program; willfully preventing, obstructing, misleading, or delaying a criminal investigation of a healthcare offense; and knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items, or services. Similar to the 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 federal Physician Payment Sunshine Act, enacted as part of the ACA, which imposes annual reporting requirements for certain manufacturers of drugs, devices, biological products, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, for certain payments and "transfers of value" provided to "covered recipients," which include U.S.-licensed physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members. For reports submitted to CMS on or after January 1, 2022, such obligations will include the reporting of payments and other transfers of value provided in the previous year to certain other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants and certified nurse midwives.

- The FDCA and PHSA, which regulate licensure of biological products and prohibit the misbranding and adulteration of biological products.

- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply with respect to healthcare items or services reimbursed by non-governmental third party-payors and may be broader than their federal equivalents; state and foreign laws requiring pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and/or the relevant compliance guidance promulgated by the federal government or otherwise restricting payments that may be made to healthcare providers; state laws and regulations requiring drug manufacturer disclosures to state agencies and/or commercial purchasers with respect to certain price increases; state and foreign laws requiring drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers and restricting marketing practices or requiring disclosure of marketing expenditures and pricing information; and state and local laws that requiring registration of pharmaceutical sales representatives.

We are also subject to the Foreign Corrupt Practices Act, or FCPA, which prohibits improper payments or offers of payments to foreign governments and their officials for the purpose of obtaining or retaining business.

Safeguards we implement to discourage improper payments or offers of payments by our employees, consultants, and others may be ineffective, and violations of the FCPA and similar state laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, any of which would likely harm our reputation, business, financial condition and results of operations.

Violations of any of these laws or any other applicable laws or regulations 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, such as Medicare and Medicaid, and imprisonment. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from its business.

*Coverage and Reimbursement*

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance, and managed healthcare organizations, and 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 payor-by-payor basis. These third-party payors are increasingly reducing coverage and reimbursement for healthcare items (including drugs) and services. Moreover, for products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used.

In addition, the U.S. government, states, and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement, and requirements for substitution of lower-cost or generic products. Adoption of price controls and cost-containment measures and adoption of more restrictive policies in jurisdictions with existing controls and measures could further limit sales of any drug product. Decreases in third-party reimbursement for any drug 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.

Moreover, as a condition of participating in, and having products covered under, certain federal healthcare programs, such as Medicare and Medicaid, we may become subject to federal laws and regulations that require pharmaceutical manufacturers to calculate and report certain pricing metrics to the government, including the Average Manufacturer Price, or AMP, and Best Price under the MDRP, the Medicare Average Sales Price, the 340B Ceiling Price, and Non-Federal AMP reported to the Department of Veteran Affairs, and with respect to Medicaid, pay statutory rebates on utilization of manufacturers' products by Medicaid beneficiaries. Compliance with these laws and regulations will require significant resources and may have a material adverse effect on our revenues.

*Healthcare Reform*

In the U.S., in March 2010, the ACA was enacted, which substantially changed the way healthcare is financed by both governmental and private payors, and significantly affected the pharmaceutical industry. The ACA contained a number of provisions, including those governing the federal healthcare programs, provider reimbursement, and healthcare 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 AMP;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- expanded beneficiary eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 138% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded the types of entities eligible for the 340B Drug Pricing Program;
- established a new methodology by which rebates owed by manufacturers under MDRP are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 70 percent point-of-sale discounts off negotiated prices of applicable branded 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;

- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" and biologic agents apportioned among these entities according to their market share in certain federal government programs;

- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending;

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

- required reporting of certain financial arrangements between manufacturers of drugs, biologics, devices, and medical supplies and physicians and teaching hospitals under the federal Physician Payments Sunshine Act; and

- required annual reporting of certain information regarding drug samples that manufacturers and distributors provide to licensed practitioners.

Since its enactment, there have been executive, judicial, and legislative branch challenges to certain aspects of the ACA, and, 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 had 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, policies that create barriers to obtaining access to health insurance coverage through the ACA marketplaces. It is unclear how healthcare reform measures enacted by Congress or implemented by the Biden administration or other efforts to challenge, repeal or replace the ACA, if any, will impact the ACA.

Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. These changes include the Budget Control Act of 2011, which, among other changes, led to aggregate reductions in Medicare payments to providers of up to 2% per fiscal year that started in April 2013 and, due to subsequent legislation, will continue into 2031, with the exception of a temporary suspension of the payment reduction from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic, unless additional Congressional action is taken. Most recently, the American Rescue Plan Act of 2021 eliminates the statutory cap on drug manufacturers' MDRP rebate liability effective January 1, 2024. Under current law enacted as part of the ACA, drug manufacturers' MDRP rebate liability is capped at 100% of AMP for a covered outpatient drug.

The cost of prescription drugs has been the subject of considerable policy discussion and debate in the U.S. Congress has considered and passed legislation, and the former Trump administration pursued several regulatory reforms to further increase transparency around prices and price increases, lower out-of-pocket costs for consumers, and decrease spending on prescription drugs by government programs. Congress has also continued to conduct inquiries into the prescription drug industry's pricing practices. While several proposed reform measures will require Congress to pass legislation to become effective, Congress and the Biden administration have expressed support for legislative and/or administrative measures to address prescription drug costs. The Biden administration has also taken several executive actions that signal changes in policy from the prior administration, including with respect to executive actions by the Trump administration related to prescription drug costs. At the state level, legislatures are increasingly passing legislation and states are implementing regulations designed to control spending on, and patient out-of-pocket costs for, drug products.

We expect that additional state and federal healthcare reform and/or drug pricing measures will be adopted in the future, any of which could affect the pricing and/or availability of drug products, the amounts that federal and state governments and other third-party payors will pay for healthcare products and services, and/or our ability to generate revenue, attain or maintain profitability, or commercialize products for which we may receive regulatory approval in the future.

*Other U.S. Healthcare Laws and Compliance Requirements*

For products distributed in the United States, we will also be subject to additional healthcare regulation and enforcement by the federal government and the states in which we conduct our business.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations could be costly. Although we believe our business practices are structured to be compliant with applicable laws, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our future operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from third party payor programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians, providers or entities with whom we may do business with will be found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusion from government funded healthcare programs.

Many aspects of these laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations which increases the risk of potential violations. In addition, these laws and their interpretations are subject to change. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business, and damage our reputation.

In addition, from time to time in the future, we may become subject to additional laws or regulations administered by the FDA, the Federal Trade Commission, or by other federal, state, local or foreign regulatory authorities, to the repeal of laws or regulations that we generally consider favorable, or to more stringent interpretations of current laws or regulations. We are not able to predict the nature of such future laws, regulations, repeals or interpretations, and we cannot predict what effect additional governmental regulation, if and when it occurs, would have on our business in the future. Such developments could, however, require reformulation of certain products to meet new standards, recalls or discontinuance of certain products not able to be reformulated, additional record-keeping requirements, increased documentation of the properties of certain products, additional or different labeling, additional scientific substantiation, additional personnel, or other new requirements. Any such developments could have a material adverse effect on our business.

***Israel***

Before an entity or person can conduct clinical testing on humans in Israel, such entity or person must receive special authorization from the ethics committee (also known as a "Helsinki Committee") and general manager of the institution in which such entity or person intends to conduct its study, as required under the Guidelines for Clinical Trials in Human Subjects implemented pursuant to the Israeli Public Health Regulations (Clinical Trials in Human Subjects), as amended from time to time, and other applicable legislation. These regulations also require authorization from the Israeli Ministry of Health in certain circumstances, such as genetic trials and special fertility trials. The institutional ethics committee must, among other things, evaluate the anticipated benefits that are likely to be derived from the project to determine if it justifies the risks and inconvenience to be inflicted on the human subjects, and the committee must ensure that adequate protection exists for the rights and safety of the participants as well as the accuracy of the information gathered in the course of the clinical testing. If we perform future clinical studies in Israel, we will be required to obtain authorization from the ethics committee and general manager of each institution in which we intend to conduct our clinical trials, and in most cases, from the Israeli Ministry of Health.

***Europe and Other Territories***

Before obtaining the regulatory approval for a product (FDA or other), we must obtain approval to commence clinical trials.. For example, in the European Union, a clinical trial application, or CTA, must be submitted to each member state's national health authority and to an independent ethics committee. The CTA must be approved by both the national health authority and the independent ethics committee prior to the commencement of a clinical trial in the member state. The approval process varies

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from country to country and the time frame may be longer or shorter than that required for FDA approval. In addition, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. In all cases, clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Helsinki Declaration.

To obtain marketing approval of a drug under European Union regulatory systems, we may submit marketing authorization applications under a centralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The centralized procedure is compulsory for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, and products with a new active substance indicated for the treatment of certain diseases.It is optional for products with other new active substance (which has not been developed for the diseases named in the Annex of the relevant EU-Regulation on the authorization of medicinal products for human use and the EMA), those products that are highly innovative, or for which a centralized process is in the interest of participants. Under the centralized procedure category in the European Union, the maximum time frame for the evaluation of a marketing authorization application by the Committee of Medicinal Products for Human Use (CHMP) is 210 days after receipt of a valid application (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, for which there is no single definition, but which needs to be justified by the applicant and assessed by the CHMP on a case-by-case basis. Relevant criteria can be: the seriousness of the disease, such as seriously disabling or life-threatening diseases, to be treated; the absence or insufficiency of an appropriate alternative therapeutic approach; and anticipation of high therapeutic benefit. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days. On the basis of the CHMP opinion, the European Commission will decide on the marketing authorization within 67 days after receipt of the CHMP opinion.

The decentralized procedure provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state, known as the reference member state. Under this procedure, an applicant submits an application, or dossier, and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application (Assessment Step I). Within 90 days of receiving the reference member state's assessment report, each concerned member state must decide whether to approve the assessment report and related materials (Assessment Step II). If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the matter will be referred to the Coordination Group for Mutual Recognition Procedures and Decentralized Procedures (CMDh) at the EMA. If within 60 days of the referral a consensus is not reached, the matter and the disputed points will eventually be referred to the CHMP with EMA. The decision on whether the product can be approved is then taken by the European Commission on the basis of the opinion of the CHMP. The decision of the European Commission is binding on all member states. After the close of the procedure and review of the national translations of the texts for the labelling of the labelling, the package leaflet and the summary of product characteristics the reference member state and the concerned member states issue national marketing authorization within a further 30 days (National Step).

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCPs and the applicable regulatory requirements and the ethical principles that have their origin in the Helsinki Declaration.

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

***Intellectual Property***

We license the core intellectual property for our NanoAbs program from MPG under an exclusive license agreement, pursuant to which we received an exclusive worldwide license for the development and commercialization of NanoAbs based on certain patents and intellectual property owned by MPG and related thereto. Pursuant to the terms of the license agreement, unless earlier terminated in accordance with the provisions thereof, the license agreement will expire on a product-by-product and country-by-country basis upon the later of (i) the expiration or abandonment of the patent rights that relate to such product in such country and (ii) ten years from the date of first commercial sale of such product in such country. We have the right to license nanobodies against certain other molecular targets on the same terms described above.

**Environmental Matters**

We are subject to various environmental, health and safety laws and regulations, including those governing the use, management and disposal of hazardous, and biological materials and wastes and the cleanup of contaminated sites. We believe that our business, operations and facilities are being operated in compliance in all material respects with applicable environmental and health and safety laws and regulations. Our laboratory personnel have ongoing communication with the Israeli Ministry of Environmental Protection in order to verify compliance with relevant instructions and regulations. In addition, all of our laboratory personnel participate in instruction on the proper handling of chemicals, including hazardous substances before commencing employment, and during the course of their employment, with us. In addition, all information with respect to any chemical substance that we use is filed and stored as a Material Safety Data Sheet, as required by applicable environmental regulations. Based on information currently available to us, we do not expect environmental costs and contingencies to have a material adverse effect on us. The operation of our facilities, however, entails risks in these areas. Significant expenditures could be required in the future if we are required to comply with new or more stringent environmental or health and safety laws, regulations or requirements.

### C. Organizational Structure

We do not have any subsidiaries and do not hold any investments in other entities.

### D. Property, Plants and Equipment

Our principal executive offices and main laboratory are located at Jerusalem BioPark, 2nd floor, Hadassah Ein Kerem Campus, Jerusalem, Israel, next to Hadassah University Hospitals and Hebrew University's Medical School.

For the year ended December 31, 2023, cash outflow for our office and laboratory leases amounted to $0.4 million.

Our fixed assets are comprised of factory leasehold improvements, laboratory equipment, furniture and software. The accumulated depreciation as stated in our financial reports is deducted from the fixed assets value. Our fixed assets, less deduction for the accumulated depreciation, $10.8 million as of December 31, 2023 and $11.2 million as of December 31, 2022.

For a description of our current laboratory see Item 4B. "Business Overview – Properties ".

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## Item 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

## Item 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

### A. Operating Results

*The information contained in this section should be read in conjunction with our consolidated financial statements for the year ended December 31, 2023 and related notes and the information contained elsewhere in this annual report. Our financial statements have been prepared in accordance*

*with United States generally accepted accounting principles (U.S. GAAP) as set forth in the Financial Accounting Standards Board (the FASB) Accounting Standards Codification (ASC).*

**Company Overview**

We are a biopharmaceutical company with two complementary business units, one focused on in-house development of inflammation and immunology (I&I) biological therapeutic products beginning with an innovative, de-risked, pipeline of nanosized VHH antibodies (NanoAbs) targeting diseases with large unmet medical needs, and the other a boutique CDMO providing services to help biotech companies efficiently bring their products to market by leveraging Scinai's drug development and GMP and non-GMP manufacturing capabilities for pre-clinical and clinical studies. For financial reporting purposes, we treat our R&D business unit and our CDMO business unit as separate reporting segments.

*Development of I&I biological therapeutic products*

Since inception, we have executed eight clinical trials including a seven country, 12,400 participant phase 3 trial of its prior lead drug candidate, a universal influenza vaccine candidate ("M-001") and have built a GMP biologics manufacturing facility for biopharmaceutical products. After receiving the phase 3 trial results in Q3 2020, indicating that M-001 did not meet its clinical endpoints, we performed a turnaround process that included raising fresh capital, hiring new talent (including a new CEO), signing a research collaboration agreement with and in-licensing new intellectual property from world leading academic research institutes. Since then, we are in the process of developing a pipeline of diversified and commercially viable products built around the licensed innovative nanosized antibodies (NanoAb). NanoAbs are nanosized antibodies derived from camelid animals and are also known as VHH-antibodies or Nanobodies. "Nanobody" is a trademark registered by ABLYNX N.V., a wholly owned subsidiary of Sanofi. SCINAI has no affiliation with and is not endorsed by Sanofi.

As part of the abovementioned turnaround, on December 22, 2021, the Company signed a definitive exclusive, worldwide, License Agreement ("LA") with the Max Planck Society ("MPG"), the parent organization of the Max Planck Institute for Multidisciplinary Sciences ("MPI"), and the University Medical Center Göttingen ("UMG"), both in Gottingen, Germany, for the development and commercialization of innovative NanoAbs for the treatment of COVID-19. The agreement provides for an upfront payment, development and sales milestones and royalties based on sales and sharing of sublicense revenues. In addition, the Company signed an accompanying Research Collaboration Agreement ("aRCA") with MPG and UMG in support of the abovementioned development of a COVID-19 NanoAb by MPI and UMG. [The aRCA provided for monthly payments to MPG and UMG and had a term until the earlier of two years or the date the Company enters into first in-human clinical trials with the COVID-19 NanoAb.

On March 23, 2022, we signed a five-year Research Collaboration Agreement ("RCA"; collectively, with the LA and aRCA, the "MPG/UMG Agreements") with MPG and UMG covering the discovery, selection and characterization of NanoAbs for up to nine molecular targets that have the potential to be further developed into drug candidates for the treatment of disease indications such as psoriasis, psoriatic arthritis, asthma and wet macular degeneration. These are all large and growing markets with underserved medical needs. In each case, the molecular target has been validated as an appropriate target for therapeutic intervention through inhibition by an antibody, thereby significantly reducing the discovery work that typically entails many years of research, high cost and high risk of failure. We believe that we can leverage our NanoAbs' unique and strong binding affinity, stability at high temperatures, and potential for more effective and convenient routes of administration towards competitive commercial viability. We believe that since these are clinical validated targets, we can develop NanoAb treatments with reduced risk and cost and accelerate the time from NanoAb selection to initiation of clinical development. Each NanoAb candidate is therefore positioned as a "biobetter" piggybacking on prior discoveries of others to mitigate risk but with significant potential advantages over existing therapeutics. In addition, while each NanoAb constitutes a novel molecule for which we file patent applications thereby creating a proprietary position, all of the developed NanoAbs when viewed together constitute a pipeline that is built around the same drug discovery, development and manufacturing platform allowing us to reduce risks and save costs. SCINAI has the exclusive option for an exclusive, pre-negotiated worldwide license agreement for the development and commercialization of each of the NanoAbs covered by the RCA with MPG and UMG.

On June 5, 2023, we announced that as part of our ongoing broad-based collaboration with the Max Planck Society and the University Medical Center Gottingen (UMG), we signed an exclusive worldwide license agreement to develop and commercialize VHH antibodies (NanoAbs) targeting Interleukin-17 (IL-17) as treatments for all potential indications, starting with psoriasis and psoriatic arthritis.

In June 2023, we disclosed that we were pursuing a strategic partnership for our COVID-19 self-administered inhaled NanoAb therapeutic/prophylactic which demonstrated highly promising in vivo results in animals and that we will focus on developing the anti-IL-17 NanoAb.

*CDMO services*

On September 6, 2023, we announced the launch of a new business unit named Scinai Bioservices to serve as a CDMO offering a multitude of services to support biotech companies through process development, as well as pilot and clinical GMP manufacturing. We seek to provide high quality, yet affordable CDMO services to accelerate the drug development processes of small biotech companies, including cGMP aseptic processing required for manufacturing of clinical batches.

We lease approximately 1,850 square meters (20,000 square feet) in the Jerusalem BioPark, located in the Ein Kerem Hadassah campus, next to Hadassah University Hospital and Hebrew University's Medical School. The facility includes laboratories, offices, and upstream and downstream manufacturing suites for bulk production and limited capacity for single-dose syringe filling. We also have infrastructure to support future product manufacturing processes and equipment. The manufacturing facility features modular, single-use infrastructure, which enables us to adapt the facility to various manufacturing platforms (such as, for example, fermenters or bioreactors).

**Key Components of Statements of Operations**

***Revenues***

*Sources of revenues.* Since our inception, we have generated significant losses in connection with our research and development, clinical trials and general administrative expenses in support of our operations. During 2023 we did not generate revenues from sales of services or products. Since January 2024, our CDMO unit obtained work orders from customers with sales value of approximately $500,000.

To date, we have funded our operations primarily through (i) the sale of equity securities in both public and private offerings, (ii) a rights offering, (iii) exercises of warrants issued in connection with our initial public offering in the U.S., (iv) funding received from the IIA, and (iv) proceeds from the Finance Contract with the EIB. In February, 2021, December 2021, December 2022, September 2023 and January 2024 we raised gross proceeds of approximately $13.8 million, $9.8 million, $8 million, $1.33 million and $1.69 million respectively, in underwritten offerings of the ADSs (and, in December 2022, two warrants to purchase ADSs for each ADS offered), a registered direct of ADSs and pre-funded warrants to purchase ADSs and concurrent private placement of warrants to purchase ADSs and the exercise for a reduced exercise price of outstanding warrants to purchase ADSs in exchange for the issuance of new warrants to purchase ADSs. As of December 31, 2023, we had $4.9 million of cash and cash equivalents and short-term deposits.

We expect that we will incur additional losses soon as a result of our research and development activities. Such research and development activities will require us to obtain and expend further resources if we are to be successful. As a result, we expect to continue to incur operating losses, and we may be required to obtain additional funds to further develop our research and development programs. As a result of our research and development activities and our failure to generate revenues since our inception, among other things, our net loss for the year ended December 31, 2023 was $6.5 million.

***Operating Expenses***

*Research and development expenses*. Our research and development expenses consist primarily of salaries and related personnel expenses, fees paid to consultants, patent-related legal fees, costs of preclinical studies and clinical studies, drug and laboratory supplies, and costs for facilities and equipment. We charge all research and development expenses to operations as they are incurred. We expect our research and development expenses to remain our primary expense in the near future.

**Commented [EV28]:** Elad pleas advice

**Commented [AR29R28]:** @Eran Visepko what do you need advice on?

**Commented [EV30R28]:** language check

**Commented [PW31]:** PwC comment - The entire section is not responsive to the header "Revenue". Discuss what revenue has been generated to-date and what is expected in the near future…. Not what financings are anticipated. That last part is for the liquidity section

**Commented [AR32R31]:** @Uri Ben-Or please discuss with PwC. @Perry Wildes I did add the revenues to date from CDMO operations

**Commented [PW33R31]:** Amir, the 20-F also relates to 2023 financial results so I think we can delete the language relating to 2023.

**Commented [PW34R31]:** In any event, does the company generate revenues at the time of the work orders?

**Commented [35R31]:** what do you mean? we charge money for the work order that we do for our clients. This is revenue

@perry **:Commented [GGS36R31]**

**Commented [PW37R31]:** Did the company generate revenues at time of obtaining the work orders? If not I don't think we need the last sentence. Also the FS don't relate to 2024

**Commented [EV38]:** Should be CDMO related costs.

**Commented [SB39R38]:** Eran please provide langauge

**Commented [EV40R38]:** Elad please confirm updated langauge

Increases or decreases in research and development expenditures are attributable to the number and/or duration of the clinical studies that we conduct.

We expect that a large percentage of our research and development expenses in the future will be incurred in support of our future clinical development projects. Due to the inherently unpredictable nature of clinical development processes, we are unable to estimate with any certainty the costs we will incur. Clinical development timelines, the probability of success and development costs can differ materially from expectations.

Our future research and development expenses will depend on any Company product candidate's commercial potential. As we obtain results from clinical studies, we may elect to discontinue or delay clinical studies for any Company product candidate in certain indications in order to focus our resources on more promising product candidates. Completion of clinical studies may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of a product candidate.

The lengthy process of completing clinical studies and seeking regulatory approval for any Company product candidate requires the expenditure of substantial resources. Any failure or delay in completing clinical studies, or in obtaining regulatory approvals, could cause a delay in generating product revenue and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations. Because of the risk factors set forth above in Item 1A, we are not able to estimate with any certainty when we would recognize any net cash inflows from our projects.

Developing bio-pharmaceutical products, conducting clinical trials, obtaining commercial manufacturing capabilities and commercializing products is expensive and we will need to raise substantial additional funds to achieve our strategic objectives. Our existing cash resources are not sufficient to fund our projected cash requirements at current monthly rates for at least the next 12 months, and we will require significant additional financing in the future to fund our operations, including if and when we conduct clinical trials, obtain regulatory approval and obtain commercial manufacturing capabilities for any Company product candidate and commercialize such product candidates. Our future capital requirements will depend on many factors, including:

- the progress and costs of our clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- the amount of revenues and contributions we receive under future licensing, collaboration, development and commercialization arrangements with respect to our Company product candidates;
- the costs of the development and expansion of our operational infrastructure;
- the costs and timing of obtaining regulatory approvals for our Company product candidates;
- the ability of us, or our collaborators, to achieve development milestones, marketing approvals and other events or developments under our potential future licensing agreements;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs and timing of building and securing manufacturing arrangements for clinical or commercial production;
- the costs of contracting with third parties to provide sales and marketing capabilities for us or establishing such capabilities ourselves;
- the costs of acquiring or undertaking development and commercialization efforts for any Company product candidate or platforms;

- the magnitude of our general and administrative expenses; and
- any cost that we may incur under future in- and out-licensing arrangements relating to one or more of our Company product candidates.

Until we can generate significant recurring revenues, we expect to satisfy our future cash needs through the net proceeds received from future private or public equity raising, grants from governmental agencies such as the IIA, debt or equity or other non-dilutive financings such as the loan from EIB, among other financing mechanisms. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. If funds are not available, we may be required to delay, reduce the scope of or eliminate research or development plans for, or commercialization efforts with respect to any Company product candidate.

Since 2006, we received $6.2 million in IIA grants and Euro 24 million ($26.4 million) in EIB loans.

***Marketing, General and Administrative Expenses***

Our general and administrative expenses consist primarily of salaries and expenses related to employee benefits, including share-based compensation, for our general and administrative employees, which includes employees in executive and operational roles, including finance and human resources, as well as consulting, legal and professional services related to our general and administrative operations.

***Financial Income and Expenses***

Financial income consists primarily of interest income on our cash and cash equivalents, foreign currency exchange income, income in respect of EIB loan and warrants valuation. Financial expenses consist primarily of expenses related to bank charges foreign currency exchange expense and expenses in respect of EIB .

***Participation by Third Parties***

Our research and development expenses are net of certain participations by third parties.

Research and development grants received from the OCS, today known as the IIA, are recognized upon receipt as a liability if future economic benefits are expected from the project that will result in royalty-bearing sales. The amount of the liability for the grant is first measured at fair value using a discount rate that reflects a market rate of interest that reflects the appropriate degree of risks inherent in our business. If no economic benefits are expected from the research activity, the grant receipts are recognized as a reduction of the related research and development expenses.

At the end of each reporting period, we evaluate whether there is reasonable assurance that the received grants will not be repaid based on its best estimate of future sales and, if so, no liability is recognized and the grants are recorded against a corresponding reduction in research and development expenses.

As a result of the failure of the Phase 3 clinical trial, the Company's management estimates that there will be no future revenues from M-001. Therefore, most likely, there will be no future royalty payments to the Israel Innovation Authority ("IIA") and the European Investment Bank ("EIB").

In accordance with the EIB loan agreement as amended, the Company is required to pay EIB the principal amount of the tranches already loaned by the EIB to the Company by until December 31, 2031.

The EIB loan is recorded in the Company’s financial statements for the year ended December 31, 2023 as a liability in the amount of $19.3 million.

As of the report date, the outstanding principal amount of the EIB loan is Euro 24 million ($26.4 million).

Research and development grants received from the European Union and from the IIA are recorded against a corresponding reduction in research and development expenses.

***Taxes on Income***

Israeli resident companies, such as the Company, are generally subject to corporate tax at the rate of 23% as of 2023.

Capital gains derived by an Israeli resident company are generally subject to tax at the same rate as the corporate tax rate. Under Israeli tax legislation, a corporation will be considered as an "Israeli Resident" if it meets one of the following: (a) it was incorporated in Israel; or (b) the control and management of its business are exercised in Israel.

**Year Ended December 31, 2023 Compared to Year Ended December 31, 2022**

***Research and Development Expenses, net***

*Research and development expenses.* Our research and development expenses for the year ended December 31, 2023 amounted to $5.2 million, compared to $5.7 million for the year ended December 31, 2022. The decrease of $0.5 million was primarily due decrease in salaries and share based payments of $ 0.26 million, Max Plank related expense of $0.15 million and regulation of $0.3 million.

Our research and development expenses consist primarily of salaries and related personnel expenses, fees paid to consultants, patent-related legal fees, costs of preclinical studies and clinical studies, drug and laboratory supplies, and costs for facilities and equipment. We charge all research and development expenses to operations as they are incurred. We expect our research and development expenses to remain our primary expense in the near future. Increases or decreases in research and development expenditures are attributable to the number and/or duration of the clinical studies that we conduct.

***Marketing, General and Administrative Expenses***

Our general and administrative expenses for the year ended December 31, 2023 amounted to $4.5 million, compared to $5.3 million for the year ended December 31, 2022. The decrease of $0.8 million was primarily due decrease in salaries and share based payments of $ 0.58 million, , legal and professional services of $0.33 million offset by an increase in marketing expenses of $0.9 million.

Our general and administrative expenses consist primarily of salaries and expenses related to employee benefits, including share-based compensation, for our general and administrative employees, which includes employees in executive and operational roles, including finance and human resources, as well as consulting, legal and professional services related to our general and administrative operations.

***Financial Income, Net***

Our financial income, net for the year ended December 31, 2023 amounted to $3.2 million, primarily from Remeasurement of warrants liabilities of $4 million, Finance income in respect of loans from others of $0.05 million, offset by Exchange differences of $0.85 million.

Our financial income, net for the year ended December 31, 2022 amounted to $5.2 million primarily from Remeasurement of warrants liabilities of $0.7 million, Exchange differences of $1.53 million and Finance income in respect of loans from others of $3.2 million.

***Net Loss***

As a result of the foregoing research and development, marketing general and administrative expenses, other income, and as we have not yet generated significant revenues since our inception, our net loss for the year ended December 31, 2023 was $6.5 million, compared to our net loss for the year ended December 31, 2022 of $5.8 million.

**Year Ended December 31, 2022 Compared to Year Ended December 31, 2021**

See Item 7 of the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

**Liquidity and Capital Resources**

Since our inception, we have funded our operations primarily through public and private offerings of our equity securities in Israel and the U.S., grants from the OCS (today known as the IIA), grants received by the Israeli Ministry of Economy and European grants under the UNISEC consortium and the loan from the EIB. Information regarding the outstanding loan from the EIB is set forth above in "*Research and other Grants: Finance Contract - European Investment Bank."*

As of December 31, 2023, we had cash and cash equivalents and short-term deposits of $4.9 million as compared to $14.1 million as of December 31, 2022. Our cash and cash equivalents are denominated in US dollars.

Net cash used in operating activities was $9.4 million for the year ended December 31, 2023, compared with net cash used in operating activities of $7.3 million for the year ended December 31, 2022.

Net cash used by investing activities for the year ended December 31, 2023 was $0.64 million compared with net cash used by investing activities of $0.84 million for the year ended December 31, 2022, and primarily reflects purchase of equipment.

Net cash provided by financing activities for the year ended December 31, 2023 was $1.1 million, primarily from proceeds from issuance of warrants compared to $6.8 million as of December 31, 2022, mostly from gross proceeds from the underwritten public offerings .

As of December 31, 2023, the Company's cash and cash equivalents totaled $4,9 million. In the year ended December 31, 2023, the Company had an operating loss of $9.7 million and negative cash flows from operating activities of $9.3 million. The Company's current cash and cash equivalents position is not sufficient to fund the Company's planned operations for at least a year beyond the date of the filing date of the financial statements. Those factors raise substantial doubt about the Company's ability to continue as a going concern. The ability to continue as a going concern is dependent upon the Company obtaining the necessary financing to meet its obligations and repay its liabilities arising from normal business operations when they become due. While the Company has successfully raised funds in the past, there is no guarantee that it will be able to do so in the future. The inability to borrow or raise sufficient funds on commercially reasonable terms, would have serious consequences on our financial condition and results of operations.

The Company's current operating budget includes various assumptions concerning the level and timing of cash receipts and cash outlays for operating expenses and capital expenditures, including a cost saving plan. The Company is planning to finance its operations from its existing working capital resources and additional sources of capital and financing that are in the advanced planning phase. However, there is no assurance that additional capital and/or financing will be available to the Company, and even if available, whether it will be on terms acceptable to the Company or in amounts required. Accordingly, the Company's board of directors approved a cost saving plan, to be implemented if and as required, in whole or in part, at its discretion, to allow the Company to continue its operations and meet its cash obligations. The cost saving plan consists of cutting expenditures by means of further efficiencies and synergies, which include mainly the following steps: reduction in headcount and postponing or cancelling capital expenditures that would not be required for the implementation of the revised business plan.

The Company and the board of directors believe, however, that its existing financial resources, potential successful capital raising exercises and its operating plans, including the possible disposition of assets outside the ordinary course of business, restructuring of debt, along with the effects of the cost-saving plan, may be adequate to satisfy its expected liquidity requirements for a period of at least twelve months from the end of the filing date, although there is no guarantee.

The company financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and liabilities and commitments in the normal course of business. The financial statements for the year ended December 31, 2023, do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

On February 2, 2021, we closed an underwritten offering in which we sold 2,434,783 ADSs at a public offering price of $4.95 per ADS. On February 10, 2021, Aegis Capital Corp., the sole bookrunning manager for the underwritten offering, fully exercised its over-allotment option to purchase an additional 365,217 ADSs, bringing total gross proceeds to us from the offering including exercise of the over-allotment option of approximately $13.8 million. We received gross proceeds of $12.836 million and a net sum of $12.465 million after deduction of issuance expenses.

On December 29, 2021, we closed an underwritten offering in which it sold 4,144,068 ADSs at a public offering price of $2.36 per ADS for total proceeds of approximately $9.780 million, including ADSs acquired upon the full exercise by Aegis Capital Corp., the sole bookrunning manager for the underwritten offering, of its over-allotment option to purchase additional ADSs. The Company received gross proceeds of $9.020 million and a net sum of $8.817 million after deduction of issuance expenses.

On December 20, 2022, we closed an underwritten offering in which we sold 1,600,000 units and pre-funded units. Each unit consisted of one ADS and two warrants, each to purchase one ADS, and each pre-funded unit consisted of one pre-funded warrant to purchase one ADS and two warrants each to purchase one ADS. Each ADS (or pre-funded warrant) was sold together with two warrants at a combined purchase price of $5.00 per unit (or $4.999 per pre-funded unit after reducing $0.001 attributable to the exercise price of the pre-funded warrants). One of the warrants will expire three years from the date of issuance, and the other warrant will expire one year from the date of issuance and may be exercised for half an ADS on or prior to six (6) months following the original issuance for no additional consideration. We received gross proceeds of $7.3 million and a net sum of $7.2 million after deduction of issuance expenses.

On September 19, 2023, we closed an offering in which we issued (i) in a registered direct offering, 400,000 ADSs and pre-funded warrants to purchase up to 746,552 ADSs, at an exercise price of $0.001 per ADS, at a purchase price of $1.16 per ADS and $1.159 per pre-funded warrant, and (ii) in a concurrent private placement, unregistered warrants to purchase up to 1,146,552 ADSs. The warrants have an exercise price of $1.16 per ADS and are exercisable for a period of five and one-half years from issuance. We received gross proceeds of approximately $1.33 million and a net sum of approximately $1.0 million after deduction of placement agent fees and issuance expenses.

On January 4, 2024, we closed an offering in which we issued new unregistered warrants to purchase up to 5,213,104 ADSs in consideration for the immediate exercise of certain outstanding warrants to purchase up to an aggregate of 2,606,552 ADSs, issued by us in September 2023 and December 2022, at a reduced exercise price of $0.65 per ADS. The new warrants have an exercise price of $0.65 per ADS and have a term of exercise equal to three years or five and one-half years, as applicable, based on the term of the exercised warrants, from the date of issuance. We received gross proceeds of approximately $1.69 million and a net sum of approximately $1.42 million, after deduction of underwriter discount and issuance expenses of $275

**Trend Information**

We are a development stage company with no revenues to date. Accordingly, it is not possible for us to predict with any degree of accuracy the outcome of our research, development or commercialization efforts, or identify any significant trends, uncertainties, demands, commitments or events that are reasonably likely to have a material effect in the future on our net sales or revenues, income from continuing operations, profitability, liquidity or capital resources. However, to the extent possible, certain trends, uncertainties, demands, commitments and events are identified in the preceding subsections of this Item 5.

**E. Critical Accounting Policies**

**Commented [GGS41]:** Company to review

**Commented [EV42R41]:** Shlomi to aprrove

**Commented [PW43R41]:** Eran - did Shlomi sign off?

The preparation of financial statements and the related notes thereto included elsewhere in this annual report in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company's management believes that the estimates, judgment and assumptions used are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities at the dates of the financial statements, and the reported amount of expenses during the reporting periods. Actual results could differ from those estimates.

We believe that the following accounting policies involve a substantial degree of judgment and complexity, and accordingly, these are the policies we believe are the most critical to aid in fully understanding and evaluating our financial condition and results of operations. See also note 2 to our financial statements included elsewhere in this annual report.

*Impairment of long-lived assets*

The Company's long-lived assets are reviewed for impairment in accordance with ASC No. 360 "Property, Plant and Equipment," whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If indicators of impairment exist and the undiscounted future cash flows that the assets are expected to generate are less than the carrying value of the assets, the Company reduces the carrying amount of the assets through an impairment charge, to their estimated fair values. During the years ended December 31, 2023 and 2022, no impairment indicators have been identified.

*Fair value of financial instruments*

The accounting guidance for fair value provides a framework for measuring fair value, clarifies the definition of fair value, and expands disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

- Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

- Level 2: Observable inputs that are based on inputs not quoted on active markets but corroborated by market data.

- Level 3: Unobservable inputs are used when little or no market data are available.

## Item 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

### A. Directors and Senior Management

**Executive Officers and Directors**

We are managed by a board of directors, which is currently comprised of eight members, and our executive officers. Each of our executive officers is appointed by our board of directors. The table below sets forth our directors and executive officers. The business address for each of our executive officers and directors is c/o Scinai Immunotherapeutics Ltd., Jerusalem BioPark, 2nd floor, Hadassah Ein Kerem Campus, Jerusalem, Israel.

| Name | Age | Position |
|---|---|---|
| Amir Reichman | 48 | Chief Executive Officer and Director |
| Tamar Ben-Yedidia | 60 | Chief Scientist |
| Uri Ben-Or | 53 | Chief Financial Officer |
| Elad Mark | 42 | Chief Operating Officer |

| | | |
|---|---|---|
| Dalit Weinstein Fischer | 53 | Chief Technology Officer |
| Mark Germain | 73 | Chairman of the Board of Directors |
| Jay Green | 52 | Director |
| Morris Laster[(1) (2)] | 59 | Director |
| Yael Margolin[(1) (2)] | 71 | Director |
| Samuel Moed | 61 | Director |
| Adi Raviv[(1) (2)] | 68 | Director |
| Avner Rotman | 80 | Director |

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

***Executive Officers***

**Mr. Amir Reichman** became full-time CEO of the Company on March 2, 2021, after sharing CEO duties during a transition period beginning on January 21, 2021. Mr. Reichman served as Head of Global Vaccines Engineering Core Technologies and Asset Management at GSK Vaccines ("GSK") in Belgium from December 2017 until March 2021. Prior to this, Mr. Reichman served as Senior Director of Vaccines Supply Chain for GSK from September 2015 to November 2017. Prior to GSK, Mr. Reichman held various leadership roles of increasing responsibility in the Global Vaccines Value Chain Management organization of Novartis Vaccines and Diagnostics Ltd. ("Novartis") in Holly Springs, NC from 2011 to 2015, at which time Novartis Vaccines was acquired by GSK. In 2003, Mr. Reichman's academic research contributed to the founding of NeuroDerm Ltd. ("NeuroDerm"), an Israeli company that developed a drug device combination product aimed at transdermal drug delivery for the treatment of Parkinson's NeuroDerm was acquired by Mitsubishi Tanabe Pharma Corporation in 2017 for $1.1 billion. Mr. Reichman served as NeuroDerm's first employee and Senior Scientist until his departure for an MBA at the Wharton school in 2009. Mr. Reichman earned an M.Sc. in Biotechnology Engineering from the Ben-Gurion University of the Negev in Be'er Sheva, Israel and an MBA in Finance and Health Care Management from the Wharton School of the University of Pennsylvania in Philadelphia, PA.

**Dr. Tamar Ben-Yedidia** has served as our Chief Scientist since 2004 and is responsible for the pre-clinical and clinical development and trials of the Company. Dr. Ben-Yedidia began her career at Biotechnology General (Israel) Ltd., BTG (Rehovot), where she was employed as lab manager from 1991 to 1994. Dr. Ben-Yedidia joined the Department of Immunology at the Weizmann Institute of Science from 1994 - 2004. Dr. Ben-Yedidia was involved in two European Consortium projects related to the evaluation of different approaches for vaccination, has been invited to address conferences worldwide and is published in various scientific journals. Dr. Ben-Yedidia received her Ph.D. in immunology from the Weizmann Institute after completion of her doctoral thesis titled "A Peptide-Based Vaccine Against Influenza."

**Mr. Uri Ben-Or**, CPA, MBA, has served as our Chief Financial Officer since 2007. In January 2007, Mr. Ben-Or founded CFO Direct, in which he has served as the chief executive officer and through which he provides his services to our company. Mr. Ben-Or has over 20 years of experience and significant expertise in corporate finance, accounting, M&A transactions and IPOs, and has served as CFO with life science companies traded on the TASE, on Nasdaq and over the counter. Mr. Ben-Or holds a B.A degree in Business from the College of Administration, and a M.B.A degree from the Bar Ilan University and is a certified public accountant in Israel.

**Mr. Elad Mark** joined the Company in 2018 as Site Head and has served as Chief Operating Officer since September 2019. As COO he oversees Scinai's manufacturing facility and scale up and technology transfer activities, including potential future CMO's. Prior to joining Scinai, Mr. Mark served for more than three years at Novartis as TPM (Technical Process Manager) and Area Lead Process for a large-scale biological facility establishment in Singapore, a $800 million investment in a biologics facility focused on drug substance manufacturing based on cell culture technology, which was designed to support both clinical and commercial production of potential new products that include monoclonal antibodies for use in helping patients with autoimmune, respiratory and oncology disorders. Before that Mr. Mark served as the Head of the Engineering Department in Biopharmax Group, a company which focuses on EPCM (Engineering, Procurement, Construction and Management) in the pharmaceutical field. Mr. Mark is a principal bioprocess engineer with over 15

**Commented [GGS44]:** Printer to fix highlights

**Commented [GGS45]:** Do we intend to retain this committee?

**Commented [AR46R45]:** @Perry Wildes , we don't have this committee and we don't pay its members anymore. Please remove

**Commented [PW47R45]:** I don't recall that the board formally dissolved the committee. Do we want to do it formally?

consecutive years of biotechnology engineering experience with diverse project stages including feasibility study, conceptual and detail design, commissioning, qualification and process validation. Mr. Mark holds a B.Sc. in Engineering from the Afeka Academic College of Engineering in Tel Aviv and an MBA from the Open University of Israel.

**Dr. Dalit Weinstein Fischer** joined the Company in 2022 as VP R&D and has served as Chief Technology Officer since September, 2023. From 2019 to 2022, Dr. Weinstein Fischer served as CTO of VAYU Sense AG, specializing in improving bio-based fermentation processes with an AI-based controller, and from 2016 until 2019, she served as a Director of Biological Processes at NanoSpun Technologies Ltd. From 2015 to 2016, Dr. Weinstein Fischer led the Natural Biotechnology Systems Department at Sigma Aldrich. Dr. Weinstein Fischer holds a Ph.D. from the Hadassah Medical School, Molecular Genetics and Microbiology Department, Hebrew University of Jerusalem.

***Directors***

**Mr. Mark Germain** joined the board in 2018 and has served as the Chairman of our board of directors since 2019. Mr. Germain has been involved as a founder, director, chairman of the board of, and/or investor in, over twenty companies in the biotech field and assisted many of them in arranging corporate partnerships, acquiring technology, entering into mergers and acquisitions, and executing financings and going public transactions. He graduated from New York University School of Law in1975, Order of the Coif, and was a partner in a New York law firm practicing corporate and securities law before leaving in 1986.Since then, and until he entered the biotech field in 1991, he served in senior executive capacities, including as president of a public company that was sold in 1991. In addition to being a director of Scinai, Mr. Germain is a Managing Director at The Aentib Group, a boutique merchant bank, and served as a director on the board of Pluristem Therapeutics from 2007 through June, 2022, including time as Co-Chairman and lead independent director. He is also a co-founder and director of a number of private companies in and outside the biotech field.

**Mr. Jay Green** CPA, CA, MAcc, joined the board in 2022. He is currently the Chief Financial Officer of a privately held, Canadian-based healthcare services company, a role that he has held since January 2022. Prior to this, he completed a 19-yearcareer with GSK across several progressive leadership positions in GSK's three businesses of consumer healthcare, pharmaceuticals, and vaccines, as well as corporate development. He also led GSK's global enterprise resource planning (ERP) program, one of the largest IT-enabled business transformation programs in the company's history. Mr. Green recently served from 2014 to 2020 as Senior Vice President, Finance and CFO of GSK's global vaccines business. Since 2020, Mr. Green has served in an advisory role to Gavi for COVAX, an international initiative to support equitable distribution of COVID-19 vaccines. He is a Chartered Professional Accountant who holds a Master of Accounting from the University of Waterloo, Ontario, Canada.

**Dr. Morris Laster** has served as a member of our board of directors since November 2017. Dr. Laster is a healthcare executive and entrepreneur with 30 years of experience in the biopharmaceutical industry. His expertise lies in the identification, development, management and financing of advanced biomedical drugs and technologies. Dr. Laster is currently the CEO of Clil Medical Ltd., a biomedical consultancy company, a position he has held since 2010. Since 2013, he is a Medical Venture Partner at OurCrowd, where he has led over 40 investments. Dr. Laster has founded seven companies that have gone public in the U.S., UK or Israel. Previously, he was the founding CEO of BioLineRx Ltd. (TASE: BLRX) from 2003 to 2009. In addition, he was the chairman and CEO of Keryx Biopharmaceuticals (NASDAQ: KERX) from 1997 to 2002. Dr. Laster began his career as a VP of medical venture capital at Paramount Capital in NYC. Dr. Laster received his MD from Downstate Medical Center, Brooklyn, NY in 1990 and a BS in Biology from SUNY Albany.

**Dr. Yael Margolin** has more than 35 years of experience as senior manager, CEO and board member in venture capital and in the pharmaceutical and biotech industries, leading strategic and business planning, financing, team building, product development and corporate partnerships. From 2005 to 2019, Dr. Margolin served as President, Chief Executive Officer and director of Gamida Cell Ltd., a clinical stage biopharmaceutical company, leading the company from preclinical development through phase 3 international registration studies. Prior to that, Dr. Margolin was Vice President of Denali Ventures LLC, a venture capital firm focused on healthcare, and a program manager at Teva Pharmaceuticals. Dr. Margolin holds a bachelor of science in biology and a master of science Cum Laude

from the department of microbiology, both from Tel Aviv University in Israel, a Ph.D. From the department of membrane research at the Weitzman Institute of Science in Rehovot, Israel and was a post-doctoral associate at the Yale University School of Medicine.

**Mr. Samuel Moed** is a healthcare executive with over 35 years of experience. Mr. Moed was for seven years Head of Corporate Strategy at Bristol Myers Squibb ("BMS"), a global biopharma company, until his retirement in 2020. Prior to that role, Mr. Moed was Head of Strategy Worldwide Pharma, President of US Pharma and President of the WW Consumer Health care Business at BMS. In addition to Scinai, Mr. Moed serves on the board of Mediwound Ltd., a company that develops, manufactures and commercializes bio-therapeutic solutions for tissue repair and regeneration, is a Venture Partner at aMoon, a HealthTech and Life Sciences investment fund with Scinai's former controlling shareholder Mr. Marius Nacht as the anchor investor, and advises companies in the healthcare arena. Mr. Moed received his BA in history from Columbia University in New York City in 1985.

**Mr. Adi Raviv** is a senior financial executive with a career spanning over 35 years. Mr. Raviv founded HTI Associates LLC in 1996 and since then has served as its managing member. In the past five years, and in the capacity of a consultant on behalf of HTI, Mr. Raviv has served as a Chief Executive Officer, Chief Financial Officer and Senior Advisor, respectively, to several healthcare and related companies, and continues to serve in a CFO role in one such company. In addition, since April 2016 he has been a Principal at Capacity Funding LLC, a company providing working capital solutions to small businesses. Prior to that, Mr. Raviv served in a chief financial officer position in two other companies that provide similar types of funding alternatives from 2009 to 2016. Mr. Raviv has extensive capital markets, cash management, corporate finance, investment banking, investor relations, restructuring, tax and treasury, and transactional experience along with knowledge of the private equity and venture capital arenas. Mr. Raviv co-founded THCG, Inc., a publicly traded technology merchant banking and consulting company (where he was also CFO), and has been involved with companies in challenging startup, growth, and turnaround environments. He was also an investment banker at Lehman Brothers, Oscar Gruss and Hambros over a span of a dozen years. Mr. Raviv served on the boards of directors of many private and several public companies, as well as various non-profit entities. He received a bachelor's degree in International Relations with honors from the Hebrew University of Jerusalem and an MBA, with honors, from Columbia University in New York City.

**Professor Avner Rotman** has been a member of our board of directors since 2005 and served as the Chairman until 2019.Prof. Rotman founded Rodar Technologies Ltd. in 2000 and served as its Chief Executive Officer and Chairman of the Board until2019. Prof. Rotman also founded Bio-Dar Ltd. in 1984 and served as its President and CEO from 1985 until 2000. Prof. Rotman was also the chairman of the I-Tech incubator at Kyriat Weizmann. Prof. Rotman is the Founder and Chairman of the Foundation of Cardiovascular Research in Israel. Prof. Rotman holds a PhD in chemistry from the Weizmann Institute of Science, Israel, and an M.Sc and B.Sc in chemistry from the Hebrew University of Jerusalem, Israel. We believe that Prof. Rotman is qualified to serve on our board of directors based on his extensive experience and knowledge in the field of biotechnology and as an executive officer and director of multiple biotechnology companies.

**Our Scientific Advisory Board**

Our Scientific Advisory Board includes specialists and experts in Israel, with experience in the fields of biochemistry, infectious diseases and medical research. Our Scientific Advisory Board plays an active role in advising us with respect to our products, technology development, clinical trials and safety. Pursuant to their respective appointment letters, our advisory board members are entitled to receive the following compensation: (i) a per diem cash payment of $1,000 plus VAT (aside from Professor Ruth Arnon who is entitled to receive $1,400 plus VAT), for Scientific Advisory Board meetings attended in Israel or consultation services provided during a period longer than 4 consecutive hours, or a proportion of such amount for a partial day of less than 4 consecutive hours (aside from Professor Ruth Arnon, who shall be entitled to a full day amount or any proportion of such full day amount based on a full day being 8 hours); (ii) a per diem cash payment of $2,000 plus VAT (aside from Professor Ruth Arnon who is entitled to receive $2,400 plus VAT), per full day of Scientific Advisory Board meetings or full session consultation attended outside of Israel, provided, that, in the event travel time exceeds 48 hours, additional compensation will be provided at a rate of $1,000 per each 24 hours; and (iii) with respect to Professor Michel Revel, for occasional consultations (less than 4 consecutive hours per each consultation) which do not fall under any of the above categories, the compensation shall be calculated

based on a fee of $250 per full hour of consultation. Each member of our Scientific Advisory Board was granted options to purchase ordinary shares of our Company pursuant to their respective appointment letters.

The following table sets forth certain biographical information with respect to our Scientific Advisory Board members:

**Professor Ruth Arnon**, the head of our Scientific Advisory Board, is the inventor of the new synthetic influenza vaccine and head of Scnai's Scientific Advisory Board. Formerly Vice-President of the Weizmann Institute of Science (1988-1997), Professor Arnon is an internationally acclaimed immunologist. Along with Prof. Michael Sela, she conceptualized and developed Copaxone®, a drug for the treatment of multiple sclerosis which was approved by the FDA and is presently marketed worldwide. Prior to her appointment as Vice-President of the Weismann Institute, Prof. Arnon served as Head of the Department of Chemical Immunology and as Dean of the Faculty of Biology. From 1985 to 1994, Prof. Arnon was Director of the Weisman Institute's McArthur Center for Molecular Biology of Tropical Diseases. Prof. Arnon has made significant contributions in the fields of vaccine development, cancer research and to the study of parasitic diseases. She has served as President of the European Federation of Immunological Societies, and as Secretary-General of the International Union of Immunological Societies. Dr. Arnon is the recipient of numerous international and Israeli awards including the prestigious Israel Prize. Prof. Arnon was also the Advisor for Science to the President of Israel. She is a member of the Israel Academy of Sciences, where she served as President from 2010-2015. Prof. Arnon is the incumbent of the Paul Ehrlich Chair in Immunochemistry at the Weizmann Institute.

**Prof. Michel Revel**, has M.D. and Ph.D. degrees. Born in 1938 in France, he joined the Weizmann Institute of Science, Rehovot, Israel in 1968, where he has been a full professor since 1973, heading for several periods the Departments of Virology and of Molecular Genetics. He has been an emeritus professor since 2010. Prof. Revel is best known for his work on the mechanism of action of interferon and the cloning of the genes for human interferon beta (IFN-β) and interleukin-6 (IL-6). He developed the first efficient genetic engineering production of a protein (IFN-b) in animal cells (CHO cells). He was Chief Scientist of InterPharm (Serono group), which produced the recombinant IFN-b (Rebif), a leading drug for treatment of multiple sclerosis, now 20 years in the market and sold in 90 countries by Merck Kga. Since 2010, Prof. Revel is co-founder and Chief Scientist of Kadimastem, an Israeli company producing human tissues by differentiation of pluripotent stem cells (ESC). The first product of Kadimastem, AstroRx, has recently been approved for clinical trial in Amyotrophic Lateral Sclerosis (ALS). Kadimastem also develops ESC-derived islet-like cells for the treatment of diabetes. Prof. Revel has received the Israel Prize for Medicine in 1999 and the Emet Prize in 2004. He was elected at the Israel National Academy of Science and Humanities in 2005. He served as chairman of the National Biotechnology Committee of Israel (1999-2002).

**Professor Dr. Matthias Dobbelstein** has served as Director of the Institute of Molecular Oncology at the University Medical Center Göttingen (UMG), Germany since 2005 and is also an Associate Member of the Max Planck Institute for Multidisciplinary Sciences (MPI-NAT). He received his training as a physician at the University of Munich (LMU) and performed research as a virologist and cancer biologist at Princeton University (USA), the University of Marburg (Germany) and the University of Southern Denmark.

Professor Dobbelstein's research interests focus on principles of infections and cancer, including the application of anti-cancer drugs as antivirals, as well as alpaca-derived NanoAbs (nanosized antibodies also known as nanobodies and VHHantibodies) as therapeutics. His collaboration with Professor Dr. Dirk Görlich at MPI-NAT as highlighted in their 2021 EMBO Journal article titled "Neutralization of SARS-CoV-2 by highly potent, hyperthermostable, and mutation-tolerant nanobodies" forms the scientific basis of Scinai's exclusive license for development and commercialization of an innovative, self-administered, inhaled NanoAb for the treatment of COVID-19. As recently reported, a preclinical trial of the inhaled anti-COVID-19 NanoAbs demonstrated significantly milder illness and faster recovery in comparison to infected hamsters treated with inhaled placebo. In addition, Professor Dobbelstein, together with Professor Görlich, is collaborating with Scinai under a five-year strategic research agreement for the discovery, characterization and cloning of additional NanoAbs for the treatment of autoimmune diseases such as psoriasis, psoriatic arthritis, asthma and macular degeneration.

**Prof. George H. Lowell, M.D.** served as a member of our board of directors from 2008 to May 2023. He is also since 2019 a member of the Board of Directors and Chief Scientific Officer (CSO) of Healables Ltd., a private Israeli digital health start-up company. Prior to joining our company, Prof. Lowell served as CSO for BioDefense at GlaxoSmithkline Biologicals (2006-7) which acquired ID Biomedical Corp. (IDB) and CSO of IDB (2001-6) which acquired Intellivax Intl. Prof. Lowell served as founding CEO, President and CSO of the vaccine R&D companies he founded, Intellivax, Inc. in Baltimore and Intellivax Intl. Inc. in Montreal from 1995 until 2001. From 1974, Prof. Lowell served on active duty in the US Army Medical R&D Command (USAMRDC), retiring in 1994 with the rank of Colonel. During this period he served as consultant in pediatric infectious diseases at The Walter Reed Army Medical Center and director of his laboratories at The Walter Reed Army Institute of Research in Washington, D.C. From 1989-1991 COL Lowell served as Medical Liaison Officer attached to the US Embassy in Israel representing the USAMRDC to the IDF Medical Corps Research Unit. Prof. Lowell has held a number of academic posts, including Visiting Scientist at the Weizmann Institute of Science (Israel) and Visiting Professor, Hebrew University-Hadassah Medical Center (Israel). Prof. Lowell holds a B.A. from Yeshiva University, and an M.D. from the Albert Einstein College of Medicine of Yeshiva University. Prof. Lowell performed three years of post-doctoral training in pediatrics and pediatric infectious diseases and immunology at NYU-Bellevue Medical Center, and The Mount Sinai Medical Center, NY, NY. We believe that Prof. Lowell is qualified to serve on our board of directors based on his extensive experience and knowledge in the field of health care and years of executive leadership in the biomedical industry.

### B. Compensation

**Compensation of Directors and Executive Officers**

*Directors*

Each of our non-management directors receives a cash retainer, meeting participation fees, and equity awards, as detailed below.

Prior to August 24, 2023, each non-management director other than Mr. Germain (all such other directors, the "Independent Directors") received (i) an annual base payment of $35,000 for serving as a director; (ii) an annual fee of $5,000 for serving as a chairman of a committee (as applicable); (iii) $1,000 for attendance at each meeting of the Board or, as applicable, meetings of committees of the Board, as the case may be; and (iv) $500 for each written consent of the Board (or applicable committee) executed by such director.. Effective August 24, 2023, the annual cash compensation payable to our current and future Independent Directors in exchange for their services, is as follows:

- $35,000 for each Independent Director, which would cover such director's attendance at up to eight Board meetings per year;
- $5,000 for each member of the Company's Compensation Committee and Strategy Committee (other than the applicable committee chairperson), which would cover such member's attendance at up to eight committee meetings per year;
- $7,500 for each member of the Company's Audit Committee (other than the committee chairperson), which would cover such member's attendance at up to eight committee meetings per year;
- $7,500 for the chairperson of each of the Company's Compensation Committee and Strategy Committee, which would cover the chairperson's attendance at up to eight committee meetings per year;
- $10,000 for the chairperson of the Company's audit committee, which would cover the chairperson's attendance at up to eight committee meetings per year;
- $500 for attendance (in person or by video or other electronic means) by each director or committee member at any meeting of the Board or relevant committee in excess of eight meetings for the Board or the applicable committee; and

- $300 for each written consent of the Board or any of its committees.

Following shareholder approval, we granted equity awards to our non-management directors. In 2023, shareholders approved the option awards to each of our non-management directors. We granted to each such director (other than our chairman) options to purchase 20,000 ADSs of the Company, and to our chairman options to purchase 40,000 ADSs, all at an exercise price of $1.81, which was the higher of (i) 130% of the closing price of the Company's ADSs on June 15, 2023 (the date the Board approved this proposal) or (ii) 100% of the closing price of the Company's ADS on August 24, 2023 (the date of shareholder approval). The options vest in equal annual installments over a period of three years, commencing one year following the date of shareholder approval. The options are subject to accelerated vesting and will become immediately exercisable in the event of a change of control.

Following shareholder approval, we also cancelled options previously granted to our non-management directors and granted replacement options to these directors. In 2023, shareholders approved that all the options that were held at by non-management directors at the time of the meeting be cancelled and in exchange therefor the Company would grant each non-management director a replacement option to purchase such number of ADSs (each, a "Replacement Option") that is equal to the aggregate number of ADSs subject to the options held at the time by each non-management director. The number of ADSs underlying the Replacement Option that were issued to each non-management director in exchange for the options that were held by each such non-management director was as follows: (i) for Mr. Mark Germain, 29,071 ADSs; (ii) for Mr. Morris Laster; Mr. Adi Raviv, Professor Avner Rotman and Ms. Yael Margolin, 4,300 ADSs; (iii) Mr. Samuel Moed, 10,000 ADSs; and (iv) Mr. Jay Green, 2,500 ADSs. The exercise price of per ADS for the Replacement Options is $1.81, which was the higher of (i) 130% of the closing price of the Company's ADSs on June 15, 2023 (the date the Board approved this proposal) or (ii) 100% of the closing price of the Company's ADS on August 24, 2023 (the date of shareholders' approval). The options vest in equal annual installments over a period of three years, commencing one year following the date of shareholder approval. The options are subject to accelerated vesting and will become immediately exercisable in the event of a change of control.

**Commented [GGS48]:** Lucbro - should we include definition of change of control?

**Commented [AR49R48]:** @Steven Lipstein please advise

Pursuant to shareholder approval in 2012, incumbent directors who were serving in 2012 are entitled to a one-time bonus in connection with (i) the sale of all or substantially all of our assets or (ii) a commercialization of one of our products, in each case with aggregate proceeds of at least $10 million. The one-time bonus shall be equal to 0.5% of the proceeds received by us under the material agreement, which shall be limited an aggregate amount of NIS 50 million ($15.4 million) under our Compensation Policy.

For the year ended December 31, 2023, we paid an aggregate of approximately $540 thousand to our directors.

*Executive Officers*

The following table presents information regarding compensation actually received by our executive officers during the year ended December 31, 2023.

| Name | Base Salary or Other Payment | Value of Social Benefits (1) | Value of Equity Based Compensation Granted (2) | All Other Compensation (3) | Total |
|---|---|---|---|---|---|
| | USD Thousands | USD Thousands | USD Thousands | USD Thousands | USD Thousands |
| Mr. Amir Reichman<br>Chief Executive Officer | 520 | 31 | 365 | 11 | 927 |
| Dr. Tamar Ben-Yedidia<br>Chief Scientific Officer | 196 | 46 | 43 | 12 | 29 |
| Mr. Uri Ben-Or<br>Chief Financial Officer | 162 | 9 | 3 | - | 17 |
| | 187 | 32 | 30 | 16 | 26 |

**Commented [AR50]:** @Uri Ben-Or how was this calculated and how come it is almost 10 times more than Tammy?

**Commented [EV51R50]:** You have 138 thousand RSU 28 while Tammy have
thousands RSU
the value in the same as the share value at the day of the issuance

| | | | | | |
|---|---|---|---|---|---|
| Mr. Elad Mark<br>Chief Operating Officer | | | | | |
| Dr. Dalit Weinstein Fischer Chief Technology Officer | 160 | 38 | 18 | 16 | 232 |

(1) Includes payments to the National Insurance Institute, advanced education funds, managers' insurance and pension funds; vacation pay; and recuperations pay as mandated by Israeli law.

(2) Includes RSU's and options.

(3) Includes payments for car allowance

**Employment and Services Agreements**

Our employees are employed under the terms prescribed in their respective personal contracts, in accordance with the decisions of our management. Under these employment contracts, the employees are entitled to the social benefits prescribed by law and as otherwise provided in their personal contracts. These employment contracts each contain provisions standard for a company in our industry regarding non-competition, confidentiality of information and assignment of inventions. Under current applicable employment laws, we may not be able to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees. We also provide certain of our employees with a company car, which is leased from a leasing company, and a mobile phone and additional benefits.

Our executive officers are also employed under the terms and conditions prescribed in personal contracts. These personal contracts provide for notice periods of varying duration for termination of the agreement by us or by the relevant executive officer, during which time the executive officer will continue to receive base salary and benefits. These agreements also contain customary provisions regarding non-competition, confidentiality of information and assignment of inventions.

We have set aside or accrued a total amount of $640 thousands during 2023 to provide pension, retirement or similar benefits.

***Services Agreement with Our Chairman of the Board***

We are party to a services agreement with Mr. Germain, pursuant to which he receives a monthly payment of $12,500. Pursuant to this agreement, in May 2019, Mr. Germain was granted an option to purchase 13,071 ADSs at an exercise price of $79.80 per ADS. 25% of the options vested upon approval by shareholders, and the remainder vested in equal increments on each anniversary of the grant date and became fully vested on April 30, 2022. In May 2021, Mr. Germain was granted an option to purchase 16,000 ADSs at an exercise price of $69.50 per ADS. The options vest in equal monthly installments during a period of four (4) years commencing one (1) month following April 6, 2021 and become fully vested on April 6, 2025. The agreement, as amended to date, expires in May 2025 and provides that either party may terminate the agreement upon 90 days' written notice. In addition, in May 2022 we granted Mr. Germain a cash bonus of $90,000, and in August 2023, we granted Mr. Germain a cash bonus of $37,500. Mr. Germain voluntarily agreed to a 20% reduction in his monthly payment commencing mid-October 2024 until further notice

***Services and Employment Agreements with Our Chief Executive Officer***

Pursuant to his employment agreement entered into with us on January 20, 2021, Mr. Reichman is entitled to an annual gross salary of $350,000. During the transition period between January 20, 2021, the date the agreement was signed, and March 2, 2021, Mr. Reichman was entitled to a pro-rated portion of this amount equal to 20% of his monthly salary. Mr. Reichman voluntarily agreed to a 20% reduction in his monthly salary from mid-October 2024 until December 31, 2024.

The agreement also provides that Mr. Reichman was entitled to a one-time signing bonus at the gross lump sum amount of USD 50,000 and is eligible to receive an annual cash bonus of a gross amount

**Commented [MG52]:** We should add that I, Amir and a couple of other executives have been deferring 20% of our compensation since last October or so

**Commented [PW53R52]:** Amir/Uri - can you provide information as to which officers?

**Commented [AR54R52]:** @Perry Wildes it was myself, Tammy, Elad and Mark. But since Feb I think we resumed normal salaries. @Uri Ben-Or need to check whether we didn't pay the balance to Mark

**Commented [PW55R52]:** Uri - can you confirm for which months the salary was deferred? If normal salaries are being paid, would that include payments of amounts deferred?

**Commented [AR56R52]:** @Perry Wildes No payments of the amounts deferred. It was a salary cut

**Commented [PW57R52]:** revised based on information from Uri

**Commented [MG58]:** We should add that I, Amir and a couple of other executives have been deferring 20% of our compensation since last October or so

**Commented [PW59R58]:** Amir/Uri - can you provide information as to which officers?

**Commented [AR60R58]:** @Perry Wildes it was myself, Tammy, Elad and Mark. But since Feb I think we resumed normal salaries. @Uri Ben-Or need to check whether we didn't pay the balance to Mark

**Commented [PW61R58]:** Uri - can you confirm for which months the salary was deferred? If normal salaries are being paid, would that include payments of amounts deferred?

**Commented [AR62R58]:** @Perry Wildes No payments of the amounts deferred. It was a salary cut

equal to three to six monthly salaries to the extent Mr. Reichman meets annual objectives that shall be approved by the board of directors and by shareholders. It is currently contemplated that the annual bonus would be (i) four monthly salaries for meeting a set of baseline annual objectives, and (ii) three monthly salaries in the case of underperforming compared to such annual objectives, provided the Employee meets the baseline objectives set by the board of directors. Under extraordinary circumstances reflecting performance by Mr. Reichman significantly above all such annual objectives, the board of directors may, in its sole discretion, consider an additional cash bonus of not more than an additional three monthly salaries (up to nine monthly salaries in total). The bonus amounts and annual objectives shall be subject to the terms of the Company's Compensation Policy from time to time.

Furthermore, under the agreement Mr. Reichman is entitled to receive 60,000 restricted share units (the "RSUs") under the Company's 2018 Israeli Share Option Plan, which will vest over a period of five years, 20% to vest each year starting on January 20, 2021 (the "Commencement Date"), and would become fully vested, in accordance with the terms of the grant, on January 20,2026. The ADSs underlying the RSUs may not be sold by Mr. Reichman during the term of his employment except that, commencing on the third anniversary of the Commencement Date, sales may be made pursuant to a Rule 10b5-1 plan, with the number of RSUs sold during any one year period not exceeding five percent of the vested RSUs held by Mr. Reichman at the time of such sales (the "Resale Limits"). If Mr. Reichman's employment agreement is terminated by the Company for no cause prior to the fifth anniversary of the Commencement Date, the Resale Limits shall terminate. If Mr. Reichman's employment agreement is terminated by Mr. Reichman or terminated by the Company for cause prior to the fifth anniversary of the Commencement Date, the Resale Limits shall continue until the earlier of (i) one year after such termination, or (ii) the fifth anniversary of the Commencement Date. The RSUs would be subject to accelerated vesting in the event of a change of control.

For these purposes, a "change of control" means the first to occur of (i) a sale of all or substantially all of the assets of the Company; (ii) a merger, consolidation, or like transaction of the Company with or into another company; provided, that in the case of either clauses (i) or (ii) the Company's stockholders of record immediately prior to such transaction will, immediately after such transaction, hold less than fifty percent (50%) of the voting power of the surviving or acquiring entity, and provided further that a change of control shall not include (x) any consolidation, merger or reorganization effected to change the domicile of the Company or (y) any transaction or series of transactions effected principally for bona fide equity financing purposes in which cash is received by the Company or any successor or indebtedness of the Company is cancelled or converted or a combination thereof; (iii) the acquisition by any person, entity or group not directly or indirectly affiliated with Angels Investments in Hi Tech Ltd. ("Angels") of more than 50% of the voting power of the Company, in a single or series of related transactions; and (iv) when a person, entity or group not directly or indirectly affiliated with Angels becomes a shareholder that has "control," as defined in the Israeli Companies Law, 1999.

The Company will provide Mr. Reichman other benefits, such as a company car, vacation, sick days, contribution towards work disability insurance, monthly contributions equal to 7.5% of monthly salary to an Education Fund ("Keren Hishtalmut", a short-term savings plan available in Israel which is tax free to the employee up to a cap determined by law) and a manager's insurance policy or a pension fund and other benefits and perquisites similar to those of other officers of the Company.

Each of Mr. Reichman and the Company may terminate Mr. Reichman's employment by prior written notice of 60 days. In the event of termination by the Company without cause, the Company will pay Mr. Reichman nine monthly salaries, which includes amounts accrued in a pension insurance policy and amounts required by Israeli law.

In May 2022, we granted Mr. Reichman an annual bonus for the year 2021 of $250,266. In March 2023, we granted Mr. Reichman an annual cash bonus for the year 2022 of $182,000, equal to 50% of his annual base compensation) and, 78,125 RSUs that vest in three years. In January, 2024, subject to shareholder approval, we granted Mr. Reichman, 179,094 RSUs that would vest over a period of three years.

***Services and Employment Agreements with Our Chief Scientific Officer***

Pursuant to her employment agreement entered into with us on March 15, 2005, as amended to date, Dr. Ben-Yedidia is employed on a full-time basis and is currently entitled to a monthly salary of NIS 49,000 plus Company car (approximately$13,500) which also includes monthly contributions equal to 7.5% of her monthly salary to an Education Fund and a manager's insurance policy and other benefits and perquisites similar to those of other officers of the Company. In addition, we provide Dr. Ben-Yedidia with a leased company car and a mobile phone. Dr. Ben-Yedidia is entitled to 22 annual paid vacation days. Dr. Ben-Yedidia voluntarily agreed to a 20% reduction in his monthly salary from mid-October 2024 until December 31, 2024.

Dr. Ben-Yedidia's employment agreement may be terminated by either us or Dr. Ben-Yedidia upon 120 days' prior written notice or by us immediately for cause (i.e., termination due to embezzlement of our funds, or the material breach of the terms and conditions of the employment agreement, or if Dr. Ben-Yedidia is involved in an act which constitutes a breach of trust between her and us or constitutes a severe breach of discipline, or conduct causing grave injury to us any, monetarily or otherwise, or Dr. Ben-Yedidia's inability to carry out her duties for a period exceeding 120 consecutive days, provided that her resumption of duties for a period of less than 15 consecutive days shall not be deemed to have broken the continuity of the aforementioned 120 days). Under her employment agreement, Dr. Ben-Yedidia received options to purchase 25,000 ordinary shares, which were later exchanged for7,850 RSUs.

In addition, in February 2012 our board of directors approved the grant of the following conditioned bonus to Tamar Ben-Yedidia: in the event that we duly enter into one or more material agreement(s) (i.e. an agreement or a series of agreements, pertaining to a transaction with us (or any other entity designated by us for the transaction by us) in connection with the sale of all or substantially all of our assets or a commercialization of one of our products in the field of business, with aggregate proceeds received resultant of such agreement are no less than a sum of $10 million) with any third party during the term of Dr. Ben-Yedidia's engagement with us or during a period of three years commencing on the date of the termination of the employment agreement by us, Dr. Ben-Yedidia shall be entitled to receive a one-time bonus per material agreement equal to 1.25% of the proceeds received by us as a result of the material agreement. In May 2022, Dr. Ben-Yedidia was granted a 2021 bonus of NIS140,250 (approximately $43,800), an amount equal to three months' salary and 37,500 RSUs vesting in three years. For the year 2022, Dr. Ben-Yedidia was granted a performance-based incentive package of NIS 147,000 (approximately $42,000), an amount equal to 25% of her annual compensation, and a grant of 20,082 RSUs vesting in three years. In January 2024, Dr. Ben-Yedidia was granted 54,206 RSUs which will vest over three years.

**Commented [AR63]:** @Perry Wildes and @Uri Ben-Or where the RSU grant for Tammy granted in 2022 for her 2021 performance?

**Commented [SB64R63]:** added

***Services and Employment Agreement with Our Chief Financial Officer***

Pursuant to the service agreement entered into on June 20, 2007, between us, Mr. Ben-Or and CFO Direct, an Israeli company solely owned by him through which he provides his services to us, as amended to dateCFO Direct is entitled to a monthly fee of NIS 30,000. The service agreement rmay be terminated by either us or CFO Direct with 60 days prior written notice. We may terminate our service agreement with CFO Direct at any time and effective immediately, without need for prior written notice, and without derogating from any other remedy to which we may be entitled, for cause (i.e., termination due to the conviction of CFO Direct and/or Uri Ben-Or of any felony, the liability of CFO Direct by a court of competent jurisdiction for fraud against us, any conduct that has a material adverse effect or is materially detrimental to us, including but not limited to, a breach of contract or any claim by CFO direct or any one connect thereto that CFO Direct is our employee).

In addition, pursuant to a separate employment agreement entered into between us and Mr. Ben-Or on August 31, 2014 and extended on June 11, 2020, Mr. Ben-Or is also employed by us in a 60% employment capacity, for which he is entitled to a monthly salary of NIS 10,000. Mr. Ben-Or is entitled to 60% of the annual paid vacation days prescribed under applicable law, and we shall obtain and maintain with Mr. Ben-Or a pension insurance to Mr. Ben-Or, in a Managers Insurance and/or a pension fund, according to Mr. Ben-Or's discretion. Mr. Ben-Or's employment agreement may be terminated by either us or Mr. Ben-Or with 60 days prior written notice, or by us immediately for cause.

***Employment Agreement with Our Chief Operating Officer***

Pursuant to his employment agreement entered into with us and Mr. Elad Mark on September 5, 2018, he is entitled to a monthly salary of NIS 46,000 (approximately $13,000), which also includes monthly contributions equal to 7.5% of his monthly salary to an Education Fund and a manager's insurance policy and other benefits and perquisites similar to those of other officers of the Company. In addition, we provide Mr. Mark with a leased company car and a mobile phone. Mr. Mark is entitled to 16 annual paid vacation days. Mr. Mark agreed to a 20% reduction in his monthly salary from mid-October 2024 until December 31, 2024.

Mr. Mark's employment agreement may be terminated by either us or Mr. Mark upon 60 days' prior written notice or by us immediately for cause (i.e., termination due to embezzlement of our funds, or the material breach of the terms and conditions of the employment agreement, or if Mr. Mark is involved in an act which constitutes a breach of trust between his and us or constitutes a severe breach of discipline, or conduct causing grave injury to us any, monetarily or otherwise, or Mr. Mark's inability to carry out his duties for a period exceeding 120 consecutive days, provided that his resumption of duties for a period of less than15 consecutive days shall not be deemed to have broken the continuity of the aforementioned 120 days). In May 2022, Mr. Mark was granted a 2021 bonus of NIS 138,000 (approximately $37,000), an amount equal to three months' salary and 35,300 RSUs vesting in three years. For the year 2022, Mr. Mark was granted a performance-based incentive package of 138,000 NIS (approximately $39,000), an amount equal to 25% of his annual compensation, and 18,852 RSUs vesting in three years. In January 2024, Mr. Mark was granted 50,888 RSUs which vest over three years

**Equity Compensation Plans**

**2018 Israeli Share Option Plan**

The 2018 Israeli Share Option Plan (the "2018 Plan") permits the granting of options, restricted share units or allotment of shares or other equity-based awards to employees, directors, consultants, service providers and other entities which the board shall decide their services are considered valuable to the Company, under similar terms and conditions to the 2005 Plan.

Options granted under the 2018 Plan are subject to applicable vesting schedules and generally expire 10 years from the grant date.

Upon the termination of a recipient's engagement with us for any reason other than death, disability or for cause, all unvested options allocated shall automatically expire and all vested options allocated will automatically expire 90 days after the termination, unless expired earlier due to their term, or unless expiration is extended beyond termination under certain circumstance for a period not to exceed the term of the options, such as was recently approved by shareholders in connection with option grants to directors. If the recipient's engagement was terminated for cause (as defined in the 2018 Plan), the recipient's right to exercise any unexercised options, awarded and allocated in favor of such recipient, whether vested or not, will immediately cease and expire as of the date of such termination. If the recipient dies or is disabled, any vested but unexercised options will automatically expire 12 months from the termination of the engagement, unless expired earlier due to their term.

In the event that options allocated under the 2018 Plan expire or otherwise terminate in accordance with the provisions of the 2018 Plan, such expired or terminated options will become available for future grant awards and allocations under the 2018 Plan.

Restricted share units granted under the 2018 Plan are subject to applicable vesting schedules, and the Board may condition the grant or vesting of restricted share units upon the attainment of specified performance targets or such other factors as the Board may determine, in its sole discretion.

In the event of (i) the sale of all or substantially all of our assets; (ii) a sale (including an exchange) of all or substantially all of our share capital; or (iii) a merger, acquisition or reorganization of the Company with or into another corporation, then, subject to obtaining the applicable approvals of the Israeli tax authorities, unexercised awards then outstanding shall be assumed or substituted for an appropriate number of shares of the successor company subject to certain adjustments as determined by the board of directors in its sole discretion. Subject to certain conditions, the board shall also have the power to provide for immediate acceleration in a recipient's award agreement in the event of such a transaction.

The Company has reserved an unlimited amount of the issued and outstanding capital of the Company available for issuance under the 2018 Plan.

As of March 31, 2024, the Company had awarded grants under the Option Plan to acquire 100,600,200 ordinary shares represented by 251,500 ADSs.

### C. Board Practices

**Board of Directors**

Under the Companies Law and our articles of association, our board of directors shall direct the Company's policy and shall supervise the performance of the Company's Chief Executive Officer. Our board of directors may exercise all powers and may take all actions that are not specifically granted to our shareholders or to management. Our executive officers are responsible for our day-to-day management and have individual responsibilities established by our board of directors. Our Chief Executive Officer is appointed by and serves at the discretion of our board of directors, subject to an agreement with Mr. Amir Reichman. All other executive officers are also appointed by our board of directors and are subject to the terms of any applicable employment or services agreements that we may enter into with them or with certain entities through which we receive their services. Other than Mr. Reichman, who is entitled to certain termination payments under his agreement with us, none of our directors are entitled to benefits upon termination of their service.

Our board of directors has affirmatively determined that a majority of our directors are independent, in compliance with the NASDAQ Capital Market rules. The definition of independent director includes a set of statutory criteria that must be satisfied, including criteria whose aim is to ensure that there is no factor which would impair the ability of the independent director to exercise independent judgment in addition to the requirement that the board consider any factor which would impair the ability of the independent director to exercise independent judgment. Independent directors may be elected by an ordinary majority of the general shareholders meeting.

Under our articles of association, our board of directors must consist of at least three and not more than eleven directors, including any external directors to the extent required by Israeli law. Our board of directors currently consists of nine members, including our non-executive Chairman of the board of directors. Our directors, excluding the external directors, are divided into three groups, as nearly equal in number as practicable, with staggered three-year terms, each consisting of one-third of the directors, constituting our entire board of directors (other than the external directors). At each annual meeting, the three-year duration of service of one group of directors shall expire and the directors of such group will stand for election. Each of the directors or the successors elected to replace the directors of a group whose term shall have expired at such annual meeting shall be elected to hold office until the third annual meeting held after the date of his or her election and until his or her respective successor is elected. If no directors are appointed at the annual meeting, the directors appointed at the previous annual meeting will continue their service. Directors whose service period has ended may be appointed again.

Under our articles of association, our board of directors may appoint directors to fill vacancies on our board of directors, for a term of office for the remaining period of time during which the director whose service has ended was filled would have held office, or the conclusion of the term of office in accordance with our articles or any applicable law, subject to the maximum number of directors allowed under the articles of association. In addition, our shareholders may appoint an additional director/s to the Company, whether for the purpose of filling a position that was vacated or as an additional director/s.

Under the Companies Law, our board of directors must determine the minimum number of directors who are required to have accounting and financial expertise. In determining the number of directors required to have such expertise, our board of directors must consider, among other things, the type and size of the company and the scope and complexity of its operations. Our board of directors has determined that the minimum number of directors of our company who are required to have accounting and financial expertise is one. Our board of directors has determined that Adi Raviv has accounting and financial expertise and possesses professional qualifications as required under the Companies Law.

***Chairman of the Board***

Our articles of association provide that the chairman of the board is appointed and dismissed by the members of the board of directors and serves as chairman of the board throughout his term as a director, unless resolved otherwise by the board of directors. Under the Companies Law, the chief executive officer or a relative of the chief executive officer may not serve as the chairman of the board of directors, and the chairman or a relative of the chairman may not be vested with authorities of the chief executive officer without shareholder approval by special majority and for periods of time not exceeding three years each.

In addition, a person subordinated, directly or indirectly, to the chief executive officer may not serve as the chairman of the board of directors; the chairman of the board may not be vested with authorities that are granted to those subordinated to the chief executive officer; and the chairman of the board may not serve in any other position in the company or a controlled company, except as a director or chairman of a controlled company.

***External Directors***

Companies incorporated under the laws of the State of Israel whose shares are publicly traded, including companies with shares listed on the Nasdaq Capital Market, are considered public companies under Israeli law and are required to comply with various corporate governance requirements under Israeli law relating to such matters as external directors, the audit committee, the compensation committee and an internal auditor. These requirements are in addition to the corporate governance requirements imposed by the listing rules of the Nasdaq Capital Market and other applicable provisions of U.S. securities laws.

Pursuant to regulations enacted under the Israeli Companies Law, the board of directors of a public company whose shares are listed on certain non-Israeli stock exchanges, including Nasdaq, that do not have a controlling shareholder (as such term is defined in the Israeli Companies Law), may, subject to certain conditions, elect to "opt-out" of the requirements of the Israeli Companies Law regarding the election of external directors and to the composition of the audit committee and compensation committee, provided that the company complies with the requirements as to director independence and audit committee and compensation committee composition applicable to companies that are incorporated in the jurisdiction in which its stock exchange is located. In March 2023, our board of directors elected to opt-out of the Israeli Companies Law requirements to appoint external directors and related Israeli Companies Law rules concerning the composition of the audit committee and compensation committee.

The foregoing exemptions will continue to be available to us so long as: (i) we do not have a "controlling shareholder" (as such term is defined under the Israeli Companies Law), (ii) our shares are traded on a U.S. stock exchange, including Nasdaq, and (iii) we comply with the Nasdaq rules applicable to domestic U.S. companies. If in the future we were to have a controlling shareholder, we would again be required to comply with the requirements relating to external directors and composition of the audit committee and compensation committee.

Under the Israeli Companies Law, the term "controlling shareholder" means a shareholder with the ability to direct the activities of the company, other than by virtue of being an office holder. A shareholder is presumed to be a controlling shareholder if the shareholder holds 50% or more of the voting rights in a company or has the right to appoint the majority of the directors of the company or its general manager. For the purpose of approving transactions with controlling shareholders, the term "controlling shareholder" also includes any shareholder that holds 25% or more of the voting rights of the company if no other shareholder holds more than 50% of the voting rights in the company.

***Audit Committee***

Our audit committee consists of Mr. Adi Raviv, Dr. Yael Margolin and Dr. Morris Laster. Mr. Adi Raviv serves as the chairman of the audit committee.

Under the NASDAQ Capital Market corporate governance rules, we are required to maintain an audit committee consisting of at least three independent directors, each of whom is financially literate and one of whom has accounting or related financial management expertise.

All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the NASDAQ Capital Market corporate governance rules. Our board of directors has affirmatively determined that Mr. Adi Raviv is an audit committee financial expert as defined by the SEC rules and has the requisite financial experience as defined by the NASDAQ Capital Market corporate governance rules.

Each of the members of the audit committee are deemed "independent" as such term is defined in Rule 10A-3(b)(1) under the Exchange Act, which is different from the general test for independence of board and committee members.

**Audit Committee Role**

Our board of directors adopted an audit committee charter effective upon the listing of the ADSs and warrants on the NASDAQ Capital Market that set forth the responsibilities of the audit committee consistent with the rules of the SEC and the listing rules of the NASDAQ Capital Market, as well as the requirements for such committee under the Companies Law, including the following:

- oversight of our independent registered public accounting firm and recommending the engagement, compensation or termination of engagement of our independent registered public accounting firm to the board of directors in accordance with Israeli law;
- recommending the engagement or termination of the person filling the office of our internal auditor; and
- recommending the terms of audit and non-audit services provided by the independent registered public accounting firm for pre-approval by our board of directors.

Our audit committee provides assistance to our board of directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting, internal control and legal compliance functions by pre-approving the services performed by our independent accountants and reviewing their reports regarding our accounting practices and systems of internal control over financial reporting. Our audit committee also oversees the audit efforts of our independent accountants and takes those actions that it deems necessary to satisfy itself that the accountants are independent of management.

***Compensation Committee and Compensation Policy***

Compensation Committee

Our compensation committee currently consists of Mr. Adi Raviv, Dr. Yael Margolin and Dr. Morris Laster. Dr. Yael Margolin serves as the Chairman of the Compensation committee. The duties of the compensation committee include the recommendation to the company's board of directors of a policy regarding the terms of engagement of office holders, to which we refer as a compensation policy. That policy must be adopted by the company's board of directors, after considering the recommendations of the compensation committee, and will need to be brought for approval by the company's shareholders, which approval requires a special approval for Compensation as described below under "Approval of Related Party Transactions Under Israeli Law — Fiduciary Duties of Directors and Executive Officers".

Under the Companies Law, the board of directors of a public company must appoint a compensation committee and adopt a compensation policy.

Compensation Policy

The Compensation Policy must be based on certain considerations, must include certain provisions and needs to reference certain matters as set forth in the Companies Law. The Compensation Policy must be approved by the company's board of directors after considering the recommendations of the compensation committee. In addition, the Compensation Policy needs to be approved by the company's shareholders by a simple majority, provided that (i) such majority includes a majority of the votes cast by the shareholders who are not controlling shareholders and who do not have a personal interest in the matter, present and voting(abstentions are disregarded) or (ii) the votes cast by shareholders who are not controlling shareholders and who do not have a personal interest in the matter who were

present and voted against the Compensation Policy, constitute two percent or less of the voting power of the company. Such majority determined in accordance with clause (i) or (ii) is hereinafter referred to as the Compensation Majority.

To the extent a Compensation Policy is not approved by shareholders at a duly convened shareholders meeting, the board of directors of a company may override the resolution of the shareholders following a re-discussion of the matter by the board of directors and the compensation committee and for specified reasons, and after determining that despite the rejection by the shareholders, the adoption of the Compensation Policy is for the benefit of the company.

A Compensation Policy that is for a period of more than three years must be approved in accordance with the above procedure every three years.

Notwithstanding the above, the amendment of existing terms of office and employment of office holders (other than directors or controlling shareholders and their relatives, who serve as office holders) requires the approval of only the compensation committee, if such committee determines that the amendment is not material in relation to its existing terms.

Pursuant to the Companies Law and following the recommendation of our compensation committee, our board of directors approved our compensation policy, and our shareholders, in turn, approved the Compensation Policy at our annual general meeting of shareholders that was held on December 27, 2021. Our shareholders approved amendments to our compensation policy on August 24, 2023.

The Compensation Policy must serve as the basis for decisions concerning the financial terms of employment or engagement of office holders, including exculpation, insurance, indemnification or any monetary payment or obligation of payment in respect of employment or engagement. The Compensation Policy must relate to certain factors, including advancement of the Company's objectives, the Company's business plan and its long-term strategy, and creation of appropriate incentives for officeholders. It must also consider, among other things, the Company's risk management, size and the nature of its operations. The Compensation Policy must furthermore consider the following additional factors:

- the knowledge, skills, expertise and accomplishments of the relevant office holder;
- the office holder's roles and responsibilities and prior compensation agreements with him or her;
- the ratio between the cost of the terms of employment of an office holder and the cost of the compensation of the other employees of the company, including those employed through manpower companies, in particular the ratio between such cost and the average and median compensation of the other employees of the company, as well as the impact such disparities may have on the work relationships in the company;
- the possibility of reducing variable compensation, if any, at the discretion of the board of directors; and the possibility of setting a limit on the exercise value of non-cash variable equity-based compensation; and
- as to severance compensation, if any, the period of service of the office holder, the terms of his or her compensation during such service period, the company's performance during that period of service, the person's contribution towards the company's achievement of its goals and the maximization of its profits, and the circumstances under which the person is leaving the company.

The Compensation Policy must also include:

- a link between variable compensation and long-term performance and measurable criteria;
- the relationship between variable and fixed compensation, and the ceiling for the value of variable compensation;

- the conditions under which an office holder would be required to repay compensation paid to him or her if it was later shown that the data upon which such compensation was based was inaccurate and was required to be restated in the company's financial statements;

- the minimum holding or vesting period for variable, equity-based compensation; and

- maximum limits for severance compensation.

The compensation committee is responsible for (a) recommending the compensation policy to a company's board of directors for its approval (and subsequent approval by its shareholders) and (b) duties related to the compensation policy and to the compensation of a company's office holders as well as functions previously fulfilled by a company's audit committee with respect to matters related to approval of the terms of engagement of office holders, including:

- recommending whether a compensation policy should continue in effect, if the then-current policy has a term of greater than three years (approval of either a new compensation policy or the continuation of an existing compensation policy must in any case occur every three years);

- recommending to the board of directors periodic updates to the compensation policy;

- assessing implementation of the compensation policy; and

- determining whether the compensation terms of the chief executive officer of the company need not be brought to approval of the shareholders.

Our compensation committee's responsibilities include:

- reviewing and recommending overall compensation policies with respect to our Chief Executive Officers and other executive officers;

- reviewing and approving corporate goals and objectives relevant to the compensation of our Chief Executive Officers and other executive officers including evaluating their performance in light of such goals and objectives;

- reviewing and approving the granting of options and other incentive awards; and

- reviewing, evaluating and making recommendations regarding the compensation and benefits for our non-employee directors.

***Internal Auditor***

Under the Companies Law, the board of directors of an Israeli public company must appoint an internal auditor in accordance with the recommendation of the audit committee. An internal auditor may not be:

- a person (or a relative of a person) who holds more than 5% of the company's outstanding shares or voting rights;

- a person (or a relative of a person) who has the power to appoint a director or the general manager of the company;

- an office holder (including a director) of the company (or a relative thereof); or

- a member of the company's independent accounting firm, or anyone on his or her behalf.

- The role of the internal auditor is to examine, among other things, our compliance with applicable law and orderly business procedures. The audit committee is required to oversee the activities and to assess the performance of the internal auditor as well as to review the internal auditor's work plan. On October 22, 2014, we appointed Mr. Gewirtz Yisrael as our internal auditor. Mr. Gewirtz Yisrael is a certified internal auditor and a partner at Fahn Kanne & Co. Grant Thornton Israel, a certified public accounting firm in Israel.

- The board of directors shall determine the direct supervisor of the internal auditor. The internal auditor is required to submit his findings to the audit committee, unless specified otherwise by the board of directors.

**Approval of Related Party Transactions under Israeli Law**

***Fiduciary Duties of Directors and Executive Officers***

The Companies Law codifies the fiduciary duties that office holders owe to a company. Each person listed in the table under "Executive Officers and Directors" is an office holder under the Companies Law.

An office holder's fiduciary duties consist of a duty of care and a duty of loyalty. The duty of care requires an office holder to act with the level of care with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of loyalty requires that an office holder act in good faith and in the best interests of the company.

The duty of care includes a duty to use reasonable means to obtain:

- information on the advisability of a given action brought for his or her approval or performed by virtue of his or her position; and

- all other important information pertaining to any such action.

The duty of loyalty includes a duty to:

- refrain from any conflict of interest between the performance of his or her duties to the company and his or her other duties or personal affairs;

- refrain from any activity that is competitive with the company;

- refrain from exploiting any business opportunity of the company to receive a personal gain for himself or herself or others; and

- disclose to the company any information or documents relating to the company's affairs which the office holder received as a result of his or her position as an office holder.

**Disclosure of Personal Interests of an Office Holder and Approval of Certain Transactions**

The Companies Law requires that an office holder promptly disclose to the board of directors any personal interest that he or she may be aware of and all related material information or documents concerning any existing or proposed transaction with the company. An interested office holder's disclosure must be made promptly and in any event no later than the first meeting of the board of directors at which the transaction is considered. A personal interest includes an interest of any person in an act or transaction of a company, including a personal interest of such person's relative or of a corporate body in which such person or a relative of such person is a 5% or greater shareholder, director or general manager or in which he or she has the right to appoint at least one director or the general manager, but excluding a personal interest stemming from one's ownership of shares in the company. A personal interest furthermore includes the personal interest of a person for whom the office holder holds a voting proxy or the personal interest of the office holder with respect to his or her vote on behalf of a person for whom he or she holds a proxy even if such shareholder has no personal interest in the matter. An office holder is not, however, obligated to disclose a personal interest if it derives solely from the personal

interest of his or her relative in a transaction that is not considered an extraordinary transaction. Under the Companies Law, an extraordinary transaction is defined as any of the following:

- a transaction other than in the ordinary course of business;
- a transaction that is not on market terms; or
- a transaction that may have a material impact on a company's profitability, assets or liabilities.

If it is determined that an office holder has a personal interest in a transaction, approval by the board of directors is required for the transaction, unless the company's articles of association provide for a different method of approval. Our articles of association do not provide otherwise. Further, so long as an office holder has disclosed his or her personal interest in a transaction, the board of directors may approve an action by the office holder that would otherwise be deemed a breach of the duty of loyalty. However, a company may not approve a transaction or action that is adverse to the company's interest or that is not performed by the office holder in good faith. An extraordinary transaction in which an office holder has a personal interest requires approval first by the company's audit committee and subsequently by the board of directors. The compensation of, or an undertaking to indemnify or insure, an office holder who is not a director requires approval first by the company's compensation committee, then by the company's board of directors, and, if such compensation arrangement or an undertaking to indemnify or insure is inconsistent with the company's stated compensation policy or if the office holder is the Chief Executive Officer (apart from a number of specific exceptions), then such arrangement is subject to the approval of a majority vote of the shares present and voting at a shareholders meeting, provided that either: (a) such majority includes at least a majority of the shares held by all shareholders who are not controlling shareholders and do not have a personal interest in such compensation arrangement (excluding abstaining shareholders); or (b) the total number of shares of non-controlling shareholders and shareholders who do not have a personal interest in the compensation arrangement and who vote against the arrangement does not exceed 2% of the company's aggregate voting rights. We refer to this as the Special Approval for Compensation. Arrangements regarding the compensation, indemnification or insurance of a director require the approval of the compensation committee, board of directors and shareholders by ordinary majority, in that order, and under certain circumstances, a Special Approval for Compensation.

Generally, a person who has a personal interest in a matter which is considered at a meeting of the board of directors or the audit committee may not be present at such a meeting or vote on that matter unless the chairman of the relevant committee or board of directors, as applicable, determines that he or she should be present in order to present the transaction that is subject to approval. Generally, if a majority of the members of the audit committee or the board of directors, as applicable, have a personal interest in the approval of a transaction, then all directors may participate in discussions of the audit committee or the board of directors, as applicable. In the event a majority of the members of the board of directors have a personal interest in the approval of a transaction, then the approval thereof shall also require the approval of the shareholders.

**Disclosure of Personal Interests of Controlling Shareholders and Approval of Certain Transactions**

Pursuant to Israeli law, the disclosure requirements regarding personal interests that apply to directors and executive officers also apply to a controlling shareholder of a public company. In the context of a transaction involving a shareholder of the company, a controlling shareholder also includes a shareholder who holds 25% or more of the voting rights in the company if no other shareholder holds more than 45% of the voting rights in the company. For this purpose, the holdings of all shareholders who have a personal interest in the same transaction will be aggregated. The approval of the audit committee or the compensation committee, as the case may be, the board of directors and the shareholders of the company, in that order is required for (a) extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, (b) the engagement with a controlling shareholder or his or her relative, directly or indirectly, for the provision of services to the company, (c) the terms of engagement and compensation of a controlling shareholder or his or her relative who is not an office holder or (d) the employment of a controlling shareholder or his or her relative by the company, other than as an office holder (collectively referred as Transaction with a

Controlling Shareholder). In addition, such shareholder approval requires one of the following, which we refer to as a Special Majority:

- at least a majority of the shares held by all shareholders who do not have a personal interest in the transaction and who are present and voting at the meeting approving the transaction, excluding abstentions; or

- the shares voted against the transaction by shareholders who have no personal interest in the transaction and who are present and voting at the meeting do not exceed 2% of the voting rights in the company.

To the extent that any such Transaction with a Controlling Shareholder is for a period extending beyond three years, approval is required once every three years, unless, with respect to certain transactions, the audit committee determines that the duration of the transaction is reasonable given the circumstances related thereto.

Arrangements regarding the compensation, indemnification or insurance of a controlling shareholder in his or her capacity as an office holder require the approval of the compensation committee, board of directors and shareholders by a Special Majority and the terms thereof may not be inconsistent with the company's stated compensation policy.

Pursuant to regulations promulgated under the Companies Law, certain transactions with a controlling shareholder, a relative of a controlling shareholder, or a director that would otherwise require approval of a company's shareholders may be exempt from shareholder approval upon certain determinations of the audit committee and board of directors.

**Shareholder Duties**

Pursuant to the Companies Law, a shareholder has a duty to act in good faith and in a customary manner toward the company and other shareholders and to refrain from abusing his or her power in the company, including, among other things, in voting at a general meeting and at shareholder class meetings with respect to the following matters:

- an amendment to the company's articles of association;

- an increase of the company's authorized share capital;

- a merger; or

- the approval of related party transactions and acts of office holders that require shareholder approval.

In addition, a shareholder also has a general duty to refrain from discriminating against other shareholders.

Certain shareholders also have a duty of fairness toward the company. These shareholders include any controlling shareholder, any shareholder who knows that he or she has the power to determine the outcome of a shareholder vote at a general meeting or a shareholder class meeting and any shareholder who has the power to appoint or to prevent the appointment of an office holder of the company or other power towards the company. The Companies Law does not define the substance of the duty of fairness, except to state that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty to act with fairness.

**Exculpation, Insurance and Indemnification of Directors and Officers**

Under the Companies Law, a company may not exculpate an office holder from liability for a breach of the duty of loyalty. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of duty of care but only if a provision authorizing such exculpation is included in its articles of association. Our

articles of association include such a provision. The company may not exculpate in advance a director from liability arising out of a prohibited dividend or distribution to shareholders.

Under the Companies Law, a company may indemnify an office holder in respect of the following liabilities and expenses incurred for acts performed by him or her as an office holder, either pursuant to an undertaking made in advance of an event or following an event, provided its articles of association include a provision authorizing such indemnification:

- financial liability imposed on him or her in favor of another person pursuant to a judgment, including a settlement or arbitrator's award approved by a court. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such an undertaking must be limited to events which, in the opinion of the board of directors, can be reasonably foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail the abovementioned foreseen events and amount or criteria;
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder (i) as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (A) no indictment was filed against such office holder as a result of such investigation or proceeding; and (B) no financial liability, such as a criminal penalty, was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent; and (ii) in connection with a monetary sanction; and
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in proceedings instituted against him or her by the company, on its behalf, or by a third party, or in connection with criminal proceedings in which the office holder was acquitted, or as a result of a conviction for an offense that does not require proof of criminal intent.

Under the Companies Law and the Israeli Securities Law 5728-1968 (the "Israeli Securities Law"), a company may insure an office holder against the following liabilities incurred for acts performed by him or her as an office holder if and to the extent provided in the company's articles of association:

- a breach of the duty of loyalty to the company, provided that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;
- a breach of duty of care to the company or to a third party, to the extent such a breach arises out of the negligent conduct of the office holder; and
- a financial liability imposed on the office holder in favor of a third party.

Under our articles of association, we may insure an office holder against the aforementioned liabilities as well as the following liabilities:

- a breach of duty of care to the company or to a third party.
- any other action against which we are permitted by law to insure an office holder;
- expenses incurred and/or paid by the office holder in connection with an administrative enforcement procedure under any applicable law including the Efficiency of Enforcement Procedures in the Securities Authority Law (legislation amendment), 5771-2011 and the Israeli Securities Law, which we refer to as an Administrative Enforcement Procedure, and including reasonable litigation expenses and attorney fees; and

- a financial liability in favor or a victim of a felony pursuant to Section 52ND of the Israeli Securities Law.

Under the Companies Law, a company may not indemnify, exculpate or insure an office holder against any of the following:

- a breach of the duty of loyalty, except for indemnification and insurance for a breach of the duty of loyalty to the company to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;
- a breach of duty of care committed intentionally or recklessly, excluding a breach arising solely out of the negligent conduct of the office holder;
- an act or omission committed with intent to derive illegal personal benefit; or
- a fine, civil fine, administrative fine or ransom or levied against the office holder.

Under the Companies Law, exculpation, indemnification and insurance of office holders in a public company must be approved by the compensation committee and the board of directors and, with respect to certain office holders or under certain circumstances, also by the shareholders.

Our articles of association permit us to exculpate, indemnify and insure our office holders to the fullest extent permitted or to be permitted by the Companies Law and the Israeli Securities Law, including expenses incurred and/or paid by the office holder in connection with an Administrative Enforcement Procedure.

We have entered into agreements with each of our directors and executive officers exculpating them, to the fullest extent permitted by law and our articles of association and undertaking to indemnify them to the fullest extent permitted by law and our articles of association. This indemnification is limited to events determined as foreseeable by the board of directors based on our activities, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances.

The maximum indemnification amount set forth in such agreements is limited to an amount which shall not exceed 25% of our net assets based on our most recently audited or reviewed financial statements prior to actual payment of the indemnification amount. Such maximum amount is in addition to any amount paid (if paid) under insurance and/or by a third-party pursuant to an indemnification arrangement.

**D. Employees**

As of March 31, 2024, we had 31 employees, 7 of whom were employed in finance and administration and 26 of whom were employed in research and development. All Company employees are in Israel.

Israeli labor laws principally govern the length of the workday, minimum wages for employees, procedures for hiring and dismissing employees, determination of severance pay, annual leave, sick days, advance notice of termination of employment, equal opportunity and anti-discrimination laws and other conditions of employment. Subject to certain exceptions, Israeli law generally requires severance pay upon the retirement, death or dismissal of an employee, and requires us and our employees to make payments to the National Insurance Institute, which is similar to the U.S. Social Security Administration. Our employees have defined benefit pension plans that comply with applicable Israeli legal requirements, which also include the mandatory pension payments required by applicable law and allocations for severance pay.

While none of our employees are party to any collective bargaining agreements, certain provisions of the collective bargaining agreements between the Histadrut (General Federation of Labor in Israel) and the Coordination Bureau of Economic Organizations (including the Industrialists' Associations) are applicable to our employees by extension orders issued by the Israel Ministry of Economy (previously the Israeli Ministry of Trade, Industry and Labor). These provisions primarily concern the length of the workweek, pension fund benefits for all employees and for employees in the

industry section, insurance for work-related accidents, travel expenses reimbursement, holiday leave, convalescent payments and entitlement for vacation days. We generally provide our employees with benefits and working conditions beyond the required minimums. We have never experienced any employment-related work stoppages and believe our relationship with our employees is good.

### E. Share Ownership

For information regarding the share ownership of our directors and executive officers, see "Item 7.A. Major Shareholders."

### F. Disclosure Of A Registrant's Action To Recover Erroneously Awarded Compensation

Not Applicable.

## Item 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

### A. Major Shareholders

The following table sets forth certain information as of April 30, 2024 concerning the beneficial ownership of ADSs: (i) each director and director nominee, (ii) each Named Executive Officer in the Summary Compensation Table under "Executive Compensation" above, (iii) all executive officers and directors as a group, and (iv) each person (including any "group" as that term is used in Section 13(d)(3) of the Exchange Act) known by us to be the beneficial owner of 5% or more of our ADSs. The address for each of the persons below who are beneficial owners of 5% or more of our ADSs is our corporate address at Scinai Immunotherapeutics Ltd., Jerusalem BioPark, 2nd floor, Hadassah Ein Kerem Campus, Jerusalem, Israel. The information with respect to beneficial ownership of ADSs by our major shareholders is given based on information reported in such shareholder's Schedule 13G or Schedule 13D, except where more updated information was provided to us by the shareholders.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to ADSs. ADSs issuable under share options or other conversion rights that were exercisable within 60 days after April 30, 2024, are deemed outstanding for the purpose of computing the percentage ownership of the person holding the options or other conversion rights but are not deemed outstanding for the purpose of computing the percentage ownership of any other person. The percentage of ADSs beneficially owned is based on 5,811,419 ADSs outstanding as of April 30, 2024.

Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons and entities named in the table below have sole voting and investment power with respect to all ADSs that they beneficially own.

None of our shareholders has different voting rights from other shareholders. To the best of our knowledge, we are not owned or controlled, directly or indirectly, by another corporation or by any foreign government. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

Except as otherwise indicated in the footnotes to this table, we believe the persons named in this table have sole voting and investment power with respect to all the ordinary shares indicated.

**Commented [GGS65]:** Table to be completed

**Commented [GGS66R65]:** Please confirm holdings of directors; haven't RSUs vested? Conform footnotes

**Commented [AR67R65]:** @Uri Ben-Or please check vesting

Eran has confirmed that **:Commented [GGS68R65]** vesting has been reviewed

**Commented [PW69]:** PwC comment - אודה לקבלת נייר עבודה לסכומים אלה

**Commented [AR70R69]:** @Eran Visepko and @Uri Ben-Or please provide the document requested by PwC

Sent **:Commented [Ev71R69]**

| | ADSs | Percent of Class % |
|---|---|---|
| **Directors and Executive Officers** | | |
| Avner Rotman (1) | 847 | * |
| Mark Germain | - | * |
| Morris Laster (2) | 500 | * |
| Adi Raviv (3) | 500 | * |
| Yael Margolin (4) | 500 | * |
| Sam Moed | - | * |
| Amir Reichman (5) | 36,000 | * |
| Jay Green (6) | 500 | * |
| Uri Ben-Or | - | * |
| Tamar Ben-Yedidia | - | * |
| Elad Mark | - | * |
| Dalit Weinstein Fischer) | - | |
| All executive officers and directors as a group (12 people) | 38,847 | * |
| | | |
| **5% Shareholders** | | |
| Angels Investments in Hi Tech Ltd. | 427,404 | 7.35 % |
| Daniel Stone | 624,000 | 10.74 % |
| Armistice Capital, LLC (7) | 2,811,419 | 4.99 % |
| Sabby Volatility Warrant Master Fund, Ltd (8) | 2,983,657 | 4.99 % |

* Less than 1%.

(1) Consists of 680 ADSs, and 167 ADSs issuable upon settlement of vested RSUs.

(2) Consists of 333 ADSs, and 167 ADSs issuable upon settlement of vested RSUs.

(3) Consists of 333 ADSs, and 167 ADSs issuable upon settlement of vested RSUs.

(4) Consists of 333 ADSs, and 167 ADSs issuable upon settlement of vested RSUs.

(5) Consists of 24,000 ADSs and 12,000 ADSs issuable upon settlement of vested RSUs.

(6) Consists of 208 ADSs, and 292 ADSs issuable upon settlement of vested RSUs.

(7) The securities are directly held by Armistice Capital Master Fund Ltd., a Cayman Islands exempted company (the "Master Fund"), and may be deemed to be beneficially owned by: (i) Armistice Capital, LLC ("Armistice Capital"), as the investment manager of the Master Fund; and (ii) Steven Boyd, as the Managing Member of Armistice Capital. Armistice's holdings include 2,293,104 ADSs exercisable upon exercise of warrants to acquire ADSs. The warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the Selling Stockholder from exercising that portion of the warrants that would result in the Selling Stockholder and its affiliates owning, after exercise, a number of ADSs in excess of the beneficial ownership limitation. The number of Ordinary Shares set forth in the above table does not reflect the application of this limitation. The address of Armistice Capital Master Fund Ltd. is c/o Armistice Capital, LLC, 510 Madison Avenue, 7th Floor, New York, NY 10022.

(8) Sabby Management, LLC is the investment manager of Sabby Volatility Warrant Master Fund, Ltd. and shares voting and investment power with respect to these shares in this capacity. As manager of Sabby Management, LLC, Hal Mintz also shares voting and investment power on behalf of Sabby Volatility Warrant Master Fund, Ltd. The address of the Sabby Volatility Warrant Master Fund, Ltd. is c/o c/o Ogier Fiduciary Services (Cayman) Limited, 89 Nexus Way, Camana Bay, Grand Cayman KY1-9007, Cayman Islands. Each of Sabby Management, LLC and Hal Mintz disclaims beneficial ownership over the securities listed except to the extent of their pecuniary interest therein. Sabby's holdings include 2,800,000 ADSs exercisable upon exercise of warrants to acquire ADSs. The terms of the warrants preclude a holder thereof from exercising such holder's warrant, if after giving effect to the issuance of ordinary shares upon such exercise, the holder (together with the holder's affiliates and any other persons acting as a group together with the holder or any of the holder's affiliates) would beneficially own in excess of 4.99% of the number of ordinary shares outstanding immediately after giving effect to the issuance of ordinary shares issuable upon such exercise subject to certain exceptions

### B. Related Party Transactions

The following is a description of some of the transactions with related parties to which we are a party to, and which were in effect within the past three fiscal years. The descriptions provided below are summaries of the terms of such agreements and do not purport to be complete and are qualified in their entirety by the complete agreements.

We believe that we have executed all of our transactions with related parties on terms no less favorable to us than those we could have obtained from unaffiliated third parties. See "Approval of Related Party Transactions under Israeli Law."

**Indemnification Agreements**

Our articles of association permit us to exculpate, indemnify and insure our directors and officeholders to the fullest extent permitted by the Companies Law. We have obtained directors' and officers' insurance for each of our officers and directors and have entered into indemnification agreements with all of our current officers and directors.

We have entered into indemnification and exculpation agreements with each of our current office holders and directors exculpating them to the fullest extent permitted by the law and our articles of association and undertaking to indemnify them to the fullest extent permitted by the law and our articles of association, including with respect to liabilities resulting from the initial public offering in the U.S., to the extent such liabilities are not covered by insurance. On March 1, 2015, our general shareholders meeting approved the grant of an indemnification and exculpation agreement under the same terms and conditions for each of our current office holders and directors.

**Employment and Service Agreements**

We have or have had employment, service or related agreements with each member of our senior management. See Item 6.

**Family Relationships**

There are no family relationships between any members of our executive management and our directors.

### C. Interests of Experts and Counsel

Not applicable.

## Item 8. FINANCIAL INFORMATION

### A. Consolidated Statements and Other Financial Information

**Consolidated Financial Statements**

We have appended our consolidated financial statements at the end of this annual report, starting at page F-2, as part of this annual report.

**Legal Proceedings**

We are not currently involved in any litigation that we believe could have a material adverse effect on our financial condition or results of operations. There is no action, suit, or proceeding by any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of the executive officers of our Company, threatened against or affecting our Company, our ordinary shares, our officers or directors in their capacities as such, in which an adverse decision could have a material adverse effect.

**Dividend Policy**

We have never declared or paid cash dividends to our shareholders. Currently, we do not intend to pay cash dividends. We intend to reinvest any earnings in developing and expanding our business. Any future determination relating to our dividend policy will be at the discretion of our board of directors and will depend on a number of factors, including future earnings, our financial condition, operating results, contractual restrictions, capital requirements, business prospects, applicable Israeli law and other factors our board of directors may deem relevant. In addition, the distribution of dividends is limited by Israeli law, which permits the distribution of dividends only out of distributable profits except if otherwise approved by an Israeli court. In addition, if we paya dividend out of income attributed to our Benefited Enterprise during the tax exemption period, we may be subject to tax on the grossed-up amount of such income at the corporate tax rate which would have been applied to such Benefited Enterprise's income had we not enjoyed the exemption for a Benefited Enterprise.

If we pay any dividends, we will also pay such dividends to the ADS holders to the same extent as holders of our ordinary shares, subject to the terms of the deposit agreement, including the fees and expenses payable thereunder. Cash dividends on our ordinary shares, if any, will be paid to ADS holders in U.S. dollars.

**B. Significant Changes**

No significant changes have occurred since December 31, 2023, except as otherwise disclosed in this annual report.

**Item 9. THE OFFER AND LISTING**

**A. Listing Details**

Our Ordinary Shares were traded on the TASE under the symbol "BNDX" from June 18, 2007 and under the symbol "BVXV" from May 18, 2015 to February 2018 and were voluntarily delisted from trading on the TASE, effective February 2018. The ADSs have traded on the Nasdaq Capital Market under the symbol "BVXV" since May 11, 2015, and since September 7, 2023, under the symbol "SCNI". The ADS warrants issued to investors in our initial public offering in the U.S. were traded on the Nasdaq Capital Market under the symbol "BVXVW" from May 11, 2015 until May 13, 2020.

**B. Plan of Distribution**

Not applicable.

**C. Markets**

The ADSs, each representing four hundred Ordinary Shares and evidenced by an American depositary receipt, or ADR, are traded on the Nasdaq Global Market under the symbol "SCNI." The ADRs were issued pursuant to a Depositary Agreement entered into with The Bank of New York Mellon. On May 6, 2024, our board of directors approved a ratio change of the ADSs to its non-traded ordinary shares, increasing the number of ordinary shares represented by each ADS from 400 to 4,000, which is equivalent to a reverse split of 1 for 10.

**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. Articles of Association**

Our number with the Israeli Registrar of Companies is 513436105. Our purpose is set forth in our Articles of Association is to engage in every lawful purpose in the field of biotechnology.

Our authorized share capital consists of 20,000,000,000 ordinary shares, no par value each. As of December 31, 2023, there were 1,857,169,984 ordinary shares issued and outstanding (including those represented by ADSs). All of our outstanding ordinary shares are validly issued, fully paid and non-assessable. Our ordinary shares are not redeemable and do not have any preemptive rights.

***Voting Rights***

Holders of our ordinary shares have one vote for each ordinary share held on all matters submitted to a vote of shareholders at a shareholder meeting. Shareholders may vote at shareholder meetings either in person, by proxy or by written ballot. Israeli law does not allow public companies to adopt shareholder resolutions by means of written consent in lieu of a shareholder meeting. According to the Companies Law and the regulations promulgated thereunder, for purposes of determining the shareholders entitled to notice and to vote at such meeting, the board of directors may fix the record date not more than 60 nor less than four calendar days prior to the date of the meeting, provided that an announcement regarding the general meeting be given prior to the record date. Unless stipulated differently in the Companies Law or in the articles of association, all shareholders' resolutions shall be approved by a simple majority vote. Except as otherwise disclosed herein, an amendment to our articles of association requires the prior approval of the holders of at least 75% of our shares, represented and voting at a general meeting.

Our ordinary shares do not have cumulative voting rights for the election of directors. As a result, the holders of a majority of the voting power represented at a shareholders meeting have the power to elect all of our directors, subject to the special approval requirements for external directors under the Israeli Companies Law.

***Transfer of Shares***

Our ordinary shares that are fully paid for are issued in registered form and may be freely transferred under our articles of association, unless the transfer is restricted or prohibited by applicable law or the rules of a stock exchange on which the shares are traded. The ownership or voting of our ordinary shares by non-residents of Israel is not restricted in any way by our articles of association or Israeli law, except for ownership by nationals of some countries that are, or have been, in a state of war with Israel.

***The Powers of the Directors***

Our board of directors shall direct the Company's policy and shall supervise the performance of the Company's Chief Executive Officer. Pursuant to the Companies Law and our articles of association, our board of directors may exercise all powers and take all actions that are not required under law or under our articles of association to be exercised or taken by our shareholders, including the power to borrow money for company purposes.

***Amendment of share capital***

Our articles of association enable us to increase or reduce our share capital. Any such changes are subject to the provisions of the Companies Law and must be approved by a resolution duly passed by our shareholders at a general or special meeting by voting on such change in the capital. In addition, transactions that have the effect of reducing capital, such as the declaration and payment of dividends in the absence of sufficient retained earnings and profits and an issuance of shares for less than their nominal value, require a resolution of our board of directors and court approval.

***Dividends***

Under Israeli law, we may declare and pay dividends only if, upon the determination of our board of directors, there is no reasonable concern that the distribution will prevent us from being able to meet the terms of our existing and foreseeable obligations as they become due. Under the Companies Law, the distribution amount is further limited to the greater of retained earnings or earnings generated over the two most recent years legally available for distribution according to our then last reviewed or audited financial statements, provided that the date of the financial statements is not more than six months prior to the date of distribution. In the event that we do not have retained earnings or earnings generated over the two most recent years legally available for distribution, we may seek the approval of the court in order to distribute a dividend. The court may approve our request if it is determined that there is no reasonable concern that the payment of a dividend will prevent us from satisfying our existing and foreseeable obligations as they become due.

***Shareholder Meetings***

Under Israeli law, we are required to hold an annual general meeting of our shareholders once every calendar year and in any event no later than 15 months after the date of the previous annual general meeting. All meetings other than the annual general meeting of shareholders are referred to as special meetings. Our board of directors may call special meetings whenever it sees fit, at such time and place, within or outside of Israel, as it may determine. In addition, as a company whose shares are listed for trade on an exchange outside of Israel, the Companies Law provides that our board of directors is required to convene a special meeting upon the written request of (i) any two of our directors or one quarter of the directors then in office; or (ii) one or more shareholders holding, in the aggregate either (a) 10% of our issued share capital and 1% of our outstanding voting power, or (b) 10% of our outstanding voting power.

Under Israeli law, one or more shareholders holding at least 1% of the voting rights at the general meeting may request that the board of directors include a matter in the agenda of a general meeting to be convened in the future (or, with respect to a company whose shares are listed for trade on an exchange outside of Israel, such as us, 5% if the matter is the appointment or removal of a director), provided that it is appropriate to discuss such any other matter at the general meeting

Subject to the provisions of the Companies Law and the regulations promulgated thereunder, shareholders entitled to participate and vote at general meetings are the shareholders of record on a date to be decided by the board of directors. Furthermore, the Companies Law and our articles of association require that resolutions regarding the following matters must be passed at a general meeting of our shareholders:

- amendments to our articles of association;
- appointment or termination of our auditors;
- appointment of directors and appointment and dismissal of external directors;

- approval of acts and transactions requiring general meeting approval pursuant to the Companies Law;
- director compensation, indemnification and change of the principal executive officer;
- increases or reductions of our authorized share capital;
- a merger;
- the exercise of our board of directors' powers by a general meeting, if our board of directors is unable to exercise its powers and the exercise of any of its powers is required for our proper management; and
- authorizing the chairman of the board of directors or his relative to act as the company's chief executive officer or act with such authority; or authorize the company's chief executive officer or his relative to act as the chairman of the board of directors or act with such authority.

The Companies Law requires that a notice of any annual or special shareholders meeting be provided at least 21 days prior to the meeting and if the agenda of the meeting includes the appointment or removal of directors, the approval of transactions with office holders or interested or related parties, or an approval of a merger, notice must be provided at least 35 days prior to the meeting.

***Quorum***

The quorum required for our general meetings of shareholders consists of one or more shareholders present in person, by proxy or by other voting instrument in accordance with the Companies Law who hold or represent, in the aggregate, at least 10% (or, for so long we do not qualify as a foreign private issuer and for only so long as required by the Nasdaq Stock Market, 33 1/3% of the Company's outstanding ordinary shares) of the total outstanding voting rights, within half an hour from the appointed time.

A meeting adjourned for lack of a quorum is adjourned to the same day in the following week at the same time and place or on a later date if so specified in the summons or notice of the meeting. At the reconvened meeting, any number of our shareholders present in person or by proxy shall constitute a lawful quorum.

***Resolutions***

Our articles of association provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required by applicable law or by another provision of the articles of association.

Israeli law provides that a shareholder of a public company may vote in a meeting and in a class meeting by means of a written ballot in which the shareholder indicates how he or she votes on resolutions relating to the following matters:

- an appointment or removal of directors;
- an approval of transactions with office holders or interested or related parties, that require shareholder approval;
- an approval of a merger;
- authorizing the chairman of the board of directors or his relative to act as the company's chief executive officer or act with such authority; or authorize the company's chief executive officer or his relative to act as the chairman of the board of directors or act with such authority;

- any other matter that is determined in the articles of association to be voted on by way of a written ballot. Our articles of association do not stipulate any additional matters; and

- other matters which may be prescribed by Israel's Minister of Justice.

The provision allowing the vote by written ballot does not apply where the voting power of the controlling shareholder is sufficient to determine the vote.

The Companies Law provides that a shareholder, in exercising his or her rights and performing his or her obligations toward the company and its other shareholders, must act in good faith and in a customary manner, and avoid abusing his or her power. This is required when voting at general meetings on matters such as changes to the articles of association, increasing the company's registered capital, mergers and approval of certain interested or related party transactions. A shareholder also has a general duty to refrain from depriving any other shareholder of its rights as a shareholder. In addition, any controlling shareholder, any shareholder who knows that its vote can determine the outcome of a shareholder vote and any shareholder who, under such company's articles of association, can appoint or prevent the appointment of an office holder or other power towards the company, is required to act with fairness towards the company. The Companies Law does not describe the substance of this duty except that the remedies generally available upon a breach of contract will also apply to a breach of the duty to act with fairness, and, to the best of our knowledge, there is no binding case law that addresses this subject directly.

Under the Companies Law, unless provided otherwise in a company's articles of association, a resolution at a shareholders meeting requires approval by a simple majority of the voting rights represented at the meeting, in person, by proxy or written ballot, and voting on the resolution. Generally, a resolution for the voluntary winding up of the company requires the approval of holders of 75% of the voting rights represented at the meeting, in person, by proxy or by written ballot and voting on the resolution.

In the event of our liquidation, after satisfaction of liabilities to creditors, our assets will be distributed to the holders of our ordinary shares in proportion to their shareholdings. This right, as well as the right to receive dividends, may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential rights that may be authorized in the future.

***Access to Corporate Records***

Under the Companies Law, all shareholders of a company generally have the right to review minutes of the company's general meetings, its shareholders register and principal shareholders register, articles of association, financial statements and any document it is required by law to file publicly with the Israeli Companies Registrar and the ISA. Any of our shareholders may request to review any document in our possession that relates to any action or transaction with a related party, interested party or office holder that requires shareholder approval under the Companies Law. We may deny a request to review a document if we determine that the request was not made in good faith, that the document contains a commercial secret or a patent or that the document's disclosure may otherwise prejudice our interests.

***Acquisitions under Israeli Law***

*Full Tender Offer*

A person wishing to acquire shares of a public Israeli company and who would as a result hold over 90% of the target company's issued and outstanding share capital is required by the Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company. A person wishing to acquire shares of a public Israeli company and who would as a result hold over 90% of the issued and outstanding share capital of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the same class for the purchase of all of the issued and outstanding shares of the same class. If the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law (provided that a majority of the offerees that do not have a personal interest in such

tender offer shall have approved the tender offer except that if the total votes to reject the tender offer represent less than 2% of the company's issued and outstanding share capital, in the aggregate, approval by a majority of the offerees that do not have a personal interest in such tender offer is not required to complete the tender offer). However, a shareholder that had its shares so transferred may petition the court within six months from the date of acceptance of the full tender offer, whether or not such shareholder agreed to the tender or not, to determine whether the tender offer was for less than fair value and whether the fair value should be paid as determined by the court unless the acquirer stipulated in the tender offer that a shareholder that accepts the offer may not seek appraisal rights, so long as prior to the acceptance of the full tender offer, the acquirer and the company disclosed the information required by law in connection with the full tender offer. If the shareholders who did not accept the tender offer hold 5% or more of the issued and outstanding share capital of the company or of the applicable class, the acquirer may not acquire shares of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class from shareholders who accepted the tender offer.

*Special Tender Offer*

The Companies Law provides that an acquisition of shares of a public Israeli company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of 25% or more of the voting rights in the company, unless one of the exemptions in the Companies Law is met. This rule does not apply if there is already another holder of at least 25% of the voting rights in the company. Similarly, the Companies Law provides that an acquisition of shares in a public company must be made by means of a tender offer if as a result of the acquisition the purchaser would become a holder of 45% or more of the voting rights in the company, if there is no other shareholder of the company who holds 45% or more of the voting rights in the company, unless one of the exemptions in the Companies Law is met.

A special tender offer must be extended to all shareholders of a company, but the offeror is not required to purchase shares representing more than 5% of the voting power attached to the company's outstanding shares, regardless of how many shares are tendered by shareholders. A special tender offer may be consummated only if (i) at least 5% of the voting power attached to the company's outstanding shares will be acquired by the offeror and (ii) the number of shares tendered in the offer exceeds the number of shares whose holders objected to the offer.

If a special tender offer is accepted, then the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

Under regulations enacted pursuant to the Companies Law, the above special tender offer requirements may not apply to companies whose shares are listed for trading on a foreign stock exchange if, among other things, the relevant foreign laws or the rules of the stock exchange, include provisions limiting the percentage of control which may be acquired or that the purchaser is required to make a tender offer to the public. However, the Israeli Securities Authority's opinion is that such leniency does not apply with respect to companies whose shares are listed for trading on stock exchanges in the United States, including the NASDAQ Capital Market, which do not provide for sufficient legal restrictions on obtaining control or an obligation to make a tender offer to the public, therefore the special tender offer requirements shall apply to such companies.

*Merger*

The Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Companies Law are met, a majority of each party's shares voted on the proposed merger at a shareholders' meeting called with at least 35 days' prior notice.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the shares represented at the shareholders meeting that are held by parties other than the other party to the merger, or by any person who holds 25% or more of the outstanding shares or the right to appoint 25% or more of the directors of the other party, vote against

the merger. If the transaction would have been approved but for the separate approval of each class or the exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the value of the parties to the merger and the consideration offered to the shareholders.

Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of any of the parties to the merger, and may further give instructions to secure the rights of creditors.

In addition, a merger may not be completed unless at least 50 days have passed from the date that a proposal for approval of the merger was filed by each party with the Israeli Registrar of Companies and 30 days have passed from the date the merger was approved by the shareholders of each party.

*Antitakeover Measures*

The Companies Law allows us to create and issue shares having rights different from those attached to our ordinary shares, including shares providing certain preferred rights, distributions or other matters and shares having preemptive rights. As of the date of this annual report, we do not have any authorized or issued shares other than our ordinary shares. In the future, if we do create and issue a class of shares other than ordinary shares, such class of shares, depending on the specific rights that may be attached to them, may delay or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their ordinary shares. The authorization of a new class of shares will require an amendment to our articles of association which requires the prior approval of the holders of at least 75% of our shares at a general meeting. Shareholders voting in such meeting will be subject to the restrictions provided in the Companies Law as described above.

**Transfer Agent and Depositary**

The transfer agent and registrar for our ordinary shares is Vstock Transfer, LLC. The ADSs were issued pursuant to a Depositary Agreement entered into with The Bank of New York Mellon, which acts as depositary.

### C. Material Contracts

Our material agreements are (i) the license agreements and research collaboration agreements with MPG, (ii) the finance agreement with EIB, and (iii) our lease agreement for our facility in Jerusalem, each of which is described elsewhere in this Annual Report. We have not entered into any other material agreements in the two years immediately preceding the date of this Annual Report.

### D. Exchange Controls

In 1998, Israeli currency control regulations were liberalized significantly, so that Israeli residents generally may freely deal in foreign currency and foreign assets, and non-residents may freely deal in Israeli currency and Israeli assets. There are currently no Israeli currency control restrictions on remittances of dividends on the ordinary shares or the proceeds from the sale of the shares provided that all taxes were paid or withheld; however, legislation remains in effect pursuant to which currency controls can be imposed by administrative action at any time.

Non-residents of Israel may freely hold and trade our securities. Neither our articles of association nor the laws of the State of Israel restrict in any way the ownership or voting of ordinary shares by non-residents, except that such restrictions may exist with respect to citizens of countries which are in a state of war with Israel. Israeli residents are allowed to purchase our ordinary shares.

### E. Taxation

*The following description is not intended to constitute a complete analysis of all tax consequences relating to the ownership or disposition of our ordinary shares or ADSs (both referred to below as the Shares). You should consult your own tax advisor concerning the tax consequences of your*

**Commented [DL72]:** NTD: Company to confirm

**Commented [AR73R72]:** @Uri Ben-Or and @Perry Wildes what about the contract we signed with Ayana valued at $360K per year for 5 years?

**Commented [PW74R72]:** Not sure this is considered a material contract for 20-F purposes. See definition below from 20-F rules.

If a contract is the type that ordinarily accompanies the kind of business you and your subsidiaries conduct, we will consider it have been made in the ordinary course of business and will not require you to file it, unless it falls within one or more of the following categories. Even if it falls into one of these categories, you do not have to file the contract if it is immaterial in amount or significance.
(i) Any contract to which (A) directors, (B) officers, (C) promoters, (D) voting trustees or (E) security holders named in the registration statement are parties, unless the contract involves only the purchase or sale of current assets that have a determinable market price and the assets are purchased or sold at that price;
(ii) Any contract upon which your business is substantially dependent. Examples of these types of contracts might be (a) continuing contracts to sell the major part of your products or services or to purchase the major part of your requirement of goods, services or raw materials, or (b) any franchise or license or other agreement to use a patent, formula, trade secret, process or trade name if your business depends to a material extent on that patent, formula, trade secret processor trade name;
(iii) Any contract for the acquisition or sale of any property, plant or equipment if the consideration exceeds 15% of your fixed assets on a consolidated basis; or
(iv) Any material lease under which you hold part of the property described in the registration statement.

*particular situation, as well as any tax consequences that may arise under the laws of any state, local, foreign, including Israeli, or other taxing jurisdiction*.

**Material U.S. Federal Income Tax Considerations**

Commented [GGS75]: From most recent F-3; Lucbro to confirm

Commented [AR76R75]: @Steven Lipstein please confirm

The following is a summary of the material U.S. federal income tax consequences relating to the acquisition, ownership, and disposition of the Warrants and ADSs (collectively, the "Securities") by U.S. Holders, as defined below. This summary addresses solely U.S. Holders who acquire the Securities pursuant to this offering and who hold the Securities as capital assets for tax purposes. This summary is based on current provisions of the Internal Revenue Code of 1986, as amended (the "Code"), current and proposed U.S. Treasury regulations promulgated thereunder, and administrative and judicial decisions as of the date hereof, all of which are subject to change, possibly on a retroactive basis. In addition, this section is based in part upon representations of the depositary and the assumption that each obligation in the Deposit Agreement and any related agreement will be performed in accordance with its terms. This summary does not address all U.S. federal income tax matters that may be relevant to a particular holder or all tax considerations that may be relevant with respect to an investment in the Securities.

This summary does not address tax considerations applicable to a holder of the Securities that may be subject to special tax rules including, without limitation, the following:

- dealers or traders in securities, currencies, or notional principal contracts;
- banks, insurance companies, and other financial institutions;
- real estate investment trusts or regulated investment companies;
- persons or corporations subject to an alternative minimum tax;
- tax-exempt organizations;
- traders that have elected mark-to-market accounting;
- corporations that accumulate earnings to avoid U.S. tax;
- pension plans;
- investors that hold the Securities as part of a "straddle," "hedge," or "conversion transaction" with other investments;
- persons that actually or constructively own 10 percent or more of our Ordinary Shares outstanding by vote or by value;
- persons that are treated as partnerships or other pass-through entities for U.S. federal income purposes; and
- U.S. Holders whose functional currency is not the U.S. dollar.

This summary does not address the effect of any U.S. federal taxation other than U.S. federal income taxation, and does not include any discussion of state, local, or foreign tax consequences to a holder of the Securities. In addition, this summary does not include any discussion of the U.S. federal income tax consequences to any holder of Securities that is not a U.S. Holder.

**You are urged to consult your own tax advisor regarding the foreign and U.S. federal, state, and local income and other tax consequences of an investment in the Securities, including the potential effects of any proposed legislation, if enacted.**

For purposes of this summary, a "U.S. Holder" means a beneficial owner of a Security that is for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the U.S.;

- a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized in the U.S. or under the laws of the U.S., any state thereof, or the District of Columbia;

- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or

- a trust (1) if (a) a court within the U.S. is able to exercise primary supervision over the administration of the trust and (b) one or more U.S. persons have the authority to control all substantial decisions of the trust or (2) that has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

If an entity or arrangement that is classified as a partnership for U.S. federal tax purposes holds any Securities, the U.S. federal tax treatment of its partners will generally depend upon the status of the partners and the activities of the partnership. Entities or arrangements that are classified as partnerships for U.S. federal tax purposes and persons holding any Securities through such entities should consult their own tax advisors.

In general, and assuming that all obligations under the Deposit Agreement will be satisfied in accordance with the terms of the Deposit Agreement, if you hold ADSs, you will be treated as the holder of the underlying Ordinary Shares represented by those ADSs for U.S. federal income tax purposes. Accordingly, gain or loss generally will not be recognized if you exchange ADSs for the underlying Ordinary Shares represented by those ADSs.

*Distributions*

If we make any distribution with respect to the Securities, subject to the discussion under "– Passive Foreign Investment Companies" below, the gross amount of any distribution actually or constructively received by a U.S. Holder (through the Depositary) with respect to a Security will generally be taxable to the U.S. Holder as foreign-source dividend income to the extent of our current and accumulated earnings and profits as determined under U.S. federal income tax principles. The amount distributed will include the amount of any Israeli taxes withheld from such distribution, as described above under the caption "Material Tax Considerations-Israeli Tax Considerations." A U.S. Holder will not be eligible for any dividends received deduction in respect of the dividends paid by us, which deduction is otherwise available to a corporate U.S. Holder in respect of dividends received from a domestic corporation. Distributions in excess of earnings and profits will be non-taxable to the U.S. Holder to the extent of the U.S. Holder's adjusted tax basis in its Securities. Distributions in excess of such adjusted tax basis will generally be taxable to a U.S. Holder as capital gain from the sale or exchange of property as described below under "-Sale or Other Disposition of ADSs and Warrants." If we do not report to a U.S. Holder the portion of a distribution that exceeds earnings and profits, then the distribution will generally be taxable as a dividend. The amount of any distribution of property other than cash will be the fair market value of that property on the date of distribution.

Under the Code, certain qualified dividends received by non-corporate U.S. Holders will be subject to U.S. federal income tax at the preferential long-term capital gains of, currently, a maximum of 20%. This preferential income tax rate is applicable only to dividends paid by a "qualified foreign corporation" that is not a PFIC (as defined below under "– Passive Foreign Investment Companies,") for the year in which the dividend is paid or for the preceding taxable year, and only with respect to the Securities held by a qualified U.S. Holder (i.e., a non-corporate holder) for a minimum holding period (generally 61 days during the 121-day period beginning 60 days before the ex-dividend date) and certain other holding period requirements are met. If such holding period requirements are met, dividends we pay with respect to the Securities generally will be qualified dividend income. However, if we were a PFIC, dividends paid by us to individual U.S. Holders would not be eligible for the reduced income tax rate applicable to qualified dividends. As discussed below under "– Passive Foreign Investment Companies," we do not anticipate being treated as a PFIC for this year; however, there can be no assurance that we will not be treated as a PFIC for our current taxable or future taxable years. You should consult your own tax advisor regarding the availability of this preferential tax rate under your particular circumstances.

The amount of any distribution paid in a currency other than U.S. dollars (a "foreign currency"), including the amount of any withholding tax thereon, will be included in the gross income of a U.S. Holder in an amount equal to the U.S. dollar value of the foreign currency calculated by reference to the exchange rate in effect on the date of the U.S. Holder's (or, in the case of ADSs, the depositary's) receipt of the dividend, actively or constructively, regardless of whether the foreign currency is converted into U.S. dollars. If the foreign currency is converted into U.S. dollars on the date of receipt, a U.S. Holder generally should not be required to recognize a foreign currency gain or loss in respect of the dividend. If the foreign currency received in the distribution is not converted into U.S. dollars on the date of receipt, a U.S. Holder will have a basis in the foreign currency equal to its U.S. dollar value on the date of receipt. Any gain or loss on a subsequent conversion or other disposition of the foreign currency will be treated as U.S. source ordinary income or loss and will not be eligible for the preferential rate applicable to qualified dividend income.

Subject to certain conditions and limitations, any Israeli taxes withheld on dividends may be creditable against a U.S. Holder's U.S. federal income tax liability, subject to generally applicable limitations. The rules relating to foreign tax credits and the timing thereof are complex. You should consult your own tax advisors regarding the availability of a foreign tax credit in your particular situation.

*Sale, Exchange, or Other Disposition of ADSs and Warrants*

Subject to the discussion under "– Passive Foreign Investment Companies" below, a U.S. Holder that sells or otherwise disposes of its Securities will recognize gain or loss for U.S. federal income tax purposes in an amount equal to the difference between the amount realized on the sale or other disposition and such U.S. Holder's adjusted basis in the Securities. Such gain or loss generally will be capital gain or loss and will be a long-term capital gain or loss if the U.S. Holder's holding period of the Securities exceeds one year at the time of the sale or other disposition. Long-term capital gains realized by non-corporate U.S. Holders are generally subject to a preferential U.S. federal income tax rate. In general, gain or loss recognized by a U.S. Holder on the sale or other disposition of the Securities will be U.S. source gain or loss for purposes of the foreign tax credit limitation. However, if we are a PFIC, any such gain will be subject to the PFIC rules, as discussed below, rather than being taxed as a capital gain. As discussed below in "-Passive Foreign Investment Companies," we do not anticipate being a PFIC for this year; however, there can be no assurance that we will not be treated as a PFIC for our current taxable year and future taxable years.

If a U.S. Holder receives foreign currency upon a sale or exchange of the Securities, gain or loss will be recognized in the manner described above under "– Distributions." However, if such foreign currency is converted into U.S. dollars on the date received by the U.S. Holder, the U.S. Holder generally should not be required to recognize any foreign currency gain or loss on such conversion.

As discussed above under the heading "Material Tax Considerations-Israeli Tax Considerations-Taxation of Shareholders," a U.S. Holder who holds Securities through an Israeli broker or other Israeli intermediary may be subject to Israeli withholding tax on any capital gains recognized on a sale or other disposition of the Securities. Any Israeli tax paid under circumstances in which an exemption from (or a refund of or a reduction in) such tax was available will not be creditable for U.S. federal income tax purposes. U.S. Holders are advised to consult their Israeli broker or intermediary regarding the procedures for obtaining an exemption or reduction.

*Medicare Tax on Unearned Income*

Non-corporate U.S. Holders whose income exceeds certain thresholds are required to pay an additional 3.8% tax on their net investment income, which includes dividends paid on the Securities and capital gains from the sale or other disposition of the Securities.

*Passive Foreign Investment Companies*

Although we do not anticipate being treated as a passive foreign investment company ("PFIC") for this year, the treatment of the Company as a PFIC is based on the value and composition of our assets, and no assurance can be given that we will not be treated as a PFIC for U.S. federal income tax purposes for our current taxable year or future taxable years. We will be considered a PFIC for any taxable year if:

- at least 75% of our gross income for such taxable year is passive income; or

- at least 50% of the value of our assets (based on an average of the fair market values of the assets determined at the end of each quarter 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, if we own, directly or indirectly, 25% or more of the total value of the outstanding shares of another corporation, we will be treated as if we (a) held a proportionate share of the assets of such other corporation and (b) received a proportionate share of the income of such other corporation directly. Passive income generally includes, among other things, dividends, interest, rents, royalties and certain capital gain, but generally excludes rents and royalties that are derived in the active conduct of a trade or business and which are received from a person other than a related person.

A separate determination must be made each taxable year as to whether we are a PFIC (after the close of each such taxable year). Because the value of our assets for purposes of the asset test will generally be determined by reference to the market price of the ADSs and Warrants, our PFIC status will also depend in large part on the market price of the Securities, which may fluctuate significantly.

If we are a PFIC for any year during which a U.S. Holder holds any Securities, we generally will be treated as a PFIC with respect to such U.S. Holder for all succeeding years during which such U.S. Holder holds the Securities, unless we cease to be a PFIC and such U.S. Holder makes a "deemed sale" election with respect to the Securities that such U.S. Holder holds. For this purpose, a U.S. Holder that acquired an ADS through the exercise of a Warrant will be treated as holding such ADS for the period during which such Warrant was held. A U.S. Holder that makes such an election will be deemed to have sold the Securities it holds at their fair market value on the last day of the last taxable year in which we qualified as a PFIC, and any gain from such deemed sale will be subject to the U.S. federal income tax treatment described below. After the deemed sale election, the Securities with respect to which the deemed sale election was made will not be treated as shares in a PFIC unless we subsequently become a PFIC.

For each taxable year for which we are treated as a PFIC with respect to a U.S. Holder, such U.S. Holder will be subject to special tax rules with respect to any "excess distribution" it receives and any gain it realizes from a sale or other disposition (including a pledge) of the Securities, unless it makes a "mark-to-market" election or a "qualified electing fund" election discussed below. Distributions that a U.S. Holder receives in a taxable year that are greater than 125% of the average annual distributions it received during the shorter of the three preceding taxable years or its holding period for the Securities will be treated as an excess distribution. Under these special tax rules, if a U.S. Holder receives any excess distribution or realizes any gain from a sale or other disposition of the Securities:

- the excess distribution or gain will be allocated ratably over the U.S. Holder's holding period for the Securities;

- the amount of excess distribution or gain allocated to the current taxable year, and any taxable year before the first taxable year in which we were a PFIC, must be included in the U.S. Holder's gross income (as ordinary income) for the tax year of the sale or disposition; and

- the amount allocated to each other year will be subject to the highest marginal tax rate in effect with respect to such U.S. Holder for that year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to such amounts allocated to each other year.

The tax liability for amounts allocated to years before the year of disposition or "excess distribution" cannot be offset by any losses for such years. Additionally, any gains realized on the sale of the Securities cannot be treated as capital gains.

If we are treated as a PFIC with respect to a U.S. Holder for any taxable year, to the extent any of our subsidiaries are also PFICs, such U.S. Holder will be deemed to own its proportionate share of

any such subsidiaries that are PFICs, and such U.S. Holder may be subject to the rules described in the preceding two paragraphs with respect to the shares of such subsidiaries that are PFICs it will be deemed to own. As a result, a U.S. Holder may incur liability for any "excess distribution" described above if we receive a distribution from such subsidiaries that are PFICs or if we dispose of, or are deemed to dispose of, any shares in such subsidiaries that are PFICs. You should consult your own tax advisor regarding the application of the PFIC rules to any of our subsidiaries.

Alternatively, a U.S. Holder of "marketable stock" (as defined below) in a PFIC may make a mark-to-market election for such stock to elect out of the general tax treatment for PFICs discussed above. If a U.S. Holder makes a mark-to-market election for the ADSs, such U.S. Holder will include in income for each year we are a PFIC an amount equal to the excess, if any, of the fair market value of the ADSs as of the close of such U.S. Holder's taxable year over such U.S. Holder's adjusted basis in such ADSs. A U.S. Holder is allowed a deduction for the excess, if any, of the adjusted basis of the ADSs over their fair market value as of the close of the taxable year. However, deductions are allowable only to the extent of any net mark-to-market gains on the ADSs included in a U.S. Holder's income for prior taxable years. Amounts included in a U.S. Holder's income under a mark-to-market election, as well as gain on the actual sale or other disposition of the ADSs, are treated as ordinary income. Ordinary loss treatment also applies to the deductible portion of any mark-to-market loss on the ADSs, as well as to any loss realized on the actual sale or disposition of the ADSs to the extent the amount of such loss does not exceed the net mark-to-market gains previously included for the ADSs. A U.S. Holder's basis in the ADSs will be adjusted to reflect any such income or loss amounts. If a U.S. Holder makes a valid mark-to-market election, the tax rules that apply to distributions by corporations that are not PFICs will apply to distributions by us, except the lower applicable tax rate for qualified dividend income will not apply. If we cease to be a PFIC when a U.S. Holder has a mark-to-market election in effect, gain or loss realized by such U.S. Holder on the sale of the ADSs will be a capital gain or loss and taxed in the manner described above under "– Sale, Exchange, or Other Disposition of ADSs and Warrants."

The mark-to-market election is available only for "marketable stock," which is a stock that is traded in other than de minimis quantities on at least 15 days during each calendar quarter, or regularly traded, on a qualified exchange or another market, as defined in applicable U.S. Treasury regulations. Any trades that have as their principal purpose meeting this requirement will be disregarded. The ADSs are listed on Nasdaq and, accordingly, provided the ADSs are regularly traded, the mark-to-market election will be available to a U.S. Holder of ADSs if we are a PFIC. Once made, the election cannot be revoked without the consent of the IRS unless the ADSs cease to be marketable stock. If we are a PFIC for any year in which the U.S. Holder owns the ADSs but before a mark-to-market election is made, the interest charge rules described above will apply to any mark-to-market gain recognized in the year the election is made. If any of our subsidiaries are or become PFICs, the mark-to-market election will not be available with respect to the shares of such subsidiaries that are treated as owned by a U.S. Holder. Consequently, a U.S. Holder could be subject to the PFIC rules with respect to income of the lower-tier PFICs the value of which already had been taken into account indirectly via mark-to-market adjustments. You should consult your own tax advisors as to 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.

In certain circumstances, a U.S. Holder of stock in a PFIC can make a "qualified electing fund" election to mitigate some of the adverse tax consequences of holding stock in a PFIC by including in income its share of the corporation's income on a current basis. However, we do not currently intend to prepare or provide the information that would enable a U.S. Holder to make a qualified electing fund election.

Unless otherwise provided by the U.S. Treasury, each U.S. shareholder of a PFIC is required to file an annual information return on IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualifying Electing Fund) containing such information as the U.S. Treasury may require. A U.S. Holder's failure to file such annual information return could result in the imposition of penalties and the extension of the statute of limitations with respect to U.S. federal income tax. You should consult your own tax advisors regarding the requirements of filing such information returns under these rules, taking into account the uncertainty as to whether we are currently treated as or may become a PFIC.

**YOU ARE STRONGLY URGED TO CONSULT YOUR OWN TAX ADVISOR REGARDING THE IMPACT AND APPLICATION OF THE PFIC RULES ON YOUR INVESTMENT IN THE SECURITIES.**

*Backup Withholding and Information Reporting*

Payments of dividends with respect to the Securities and the proceeds from the sale, retirement, or other disposition of the Securities made by a U.S. paying agent or other U.S. intermediary will generally be reported to the IRS and to the U.S. Holder as may be required under applicable U.S. Treasury regulations. We, or an agent, a broker, or any paying agent, as the case may be, may be required to withhold tax (backup withholding), currently at the rate of 24%, if a non-corporate U.S. Holder that is not otherwise exempt fails to provide an accurate taxpayer identification number and comply with other IRS requirements concerning information reporting. Certain U.S. Holders (including, among others, corporations and tax-exempt organizations) are not subject to backup withholding. Backup withholding is not an additional tax. Any amount of backup withholding withheld may be used as a credit against your U.S. federal income tax liability or may be refunded provided that the required information is timely furnished to the IRS. U.S. Holders should consult their own tax advisors as to their qualification for exemption from backup withholding and the procedure for obtaining an exemption.

You should consult your own tax advisors regarding the backup withholding tax and information reporting rules.

*Foreign Asset Reporting*

Certain U.S. Holders who are individuals are required to report information relating to an interest in the Securities, subject to certain exceptions (including an exception for shares held in accounts maintained by financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. U.S. Holders are urged to consult their tax advisors regarding their information reporting obligations, if any, with respect to their ownership and disposition of the Securities.

**EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF AN INVESTMENT IN THE SECURITIES IN LIGHT OF SUCH INVESTOR'S PARTICULAR CIRCUMSTANCES.**

**Israeli Tax Considerations**

***General***

The following is a brief summary of the material tax consequences under Israeli law concerning the purchase, ownership and disposition of American Depositary Shares, representing Ordinary Shares, Pre-funded Warrants and Warrants (collectively, the "Shares") by persons who acquired the Shares in this offering.

This discussion does not purport to constitute a complete analysis of all potential tax consequences applicable to investors upon purchasing, owning or disposing of our Shares. In particular, this discussion does not take into account the specific circumstances of any particular investor (such as tax-exempt entities, financial institutions, certain financial companies, broker-dealers, investors that own, directly or indirectly, 10% or more of our outstanding voting rights, all of whom are subject to special tax regimes not covered under this discussion). To the extent that issues discussed herein are based on legislation that has yet to be subject to judicial or administrative interpretation, there can be no assurance that the views expressed herein will accord with any such interpretation in the future.

Potential investors are urged to consult their own tax advisors as to the Israeli or other tax consequences of the purchase, ownership, and disposition of the Shares, including, in particular, the effect of any foreign, state or local taxes.

***General Corporate Tax Structure in Israel***

Israeli resident companies are generally subject to corporate tax on their taxable income at the rate of 23% for the 2024 tax year.

***Taxation of Shareholders***

***Capital Gains***

Capital gain tax is imposed on the disposition of capital assets by an Israeli resident and on the disposition of such assets by a non-Israeli resident if those assets are either (i) located in Israel; (ii) are shares or a right to a share in an Israeli resident corporation, or (iii) represent, directly or indirectly, rights to assets located in Israel, unless an exemption is available or unless an applicable double tax treaty between Israel and the seller's country of residence provides otherwise. The Israeli Income Tax Ordinance distinguishes between "Real Gain" and the "Inflationary Surplus". "Real Gain" is the excess of the total capital gain over Inflationary Surplus generally computed on the basis of the increase in the Israeli Consumer Price Index between the date of purchase and the date of disposition. Inflationary Surplus is not currently subject to tax in Israel.

Real Gain accrued by individuals on the sale of the Shares will be taxed at the rate of 25%. However, if the individual shareholder is a "Controlling Shareholder" (i.e., a person who holds, directly or indirectly, alone or together with another, 10% or more of one of the Israeli resident company's means of control) at the time of sale or at any time during the preceding 12-month period, such gain will be taxed at the rate of 30%.

Corporate and individual shareholders dealing in securities in Israel are taxed at the tax rates applicable to business income (23% for corporations in 2024), and a marginal tax rate of up to 50% in 2024 for individuals, including an excess tax (as discussed below).

Notwithstanding the foregoing, capital gains generated from the sale of our Shares by a non-Israeli shareholder may be exempt from Israeli capital tax under the Israeli Income Tax Ordinance provided (among other conditions) that the seller does not have a permanent establishment in Israel to which the generated capital gain is attributed. However, non-Israeli resident corporations will not be entitled to the foregoing exemption if Israeli residents: (i) have a 25% or more interest in such non-Israeli corporation or (ii) are the beneficiaries of, or are entitled to, 25% or more of the revenues or profits of such non-Israeli corporation, whether directly or indirectly. In addition, such exemption would not be available to a person whose gains from selling or otherwise disposing of the securities are deemed to be business income.

In addition, the sale of the Shares may be exempt from Israeli capital gain tax under the provisions of an applicable double tax treaty. For example, the Convention Between the Government of the United States of America and the Government of the State of Israel with Respect to Taxes on Income, or the U.S.-Israel Double Tax Treaty, exempts a U.S. resident (for purposes of the U.S.-Israel Double Tax Treaty) from Israeli capital gain tax in connection with the sale of the Shares, provided (among other conditions) that: (i) the U.S. resident owned, directly or indirectly, less than 10% of the voting power of the company at any time within the 12-month period preceding such sale; (ii) the U.S. resident, being an individual, is present in Israel for a period or periods of less than 183 days during the taxable year; and (iii) the capital gain from the sale was not derived through a permanent establishment of the U.S. resident in Israel; however, under the U.S.-Israel Double Tax Treaty, the taxpayer may be permitted to claim a credit for such taxes against the U.S. federal income tax imposed with respect to such sale, exchange or disposition, subject to the limitations under U.S. law applicable to foreign tax credits.

Payers of consideration for the Ordinary Shares, including the purchaser, the Israeli stockbroker or the financial institution through which the Shares are held, are generally obligated, subject to certain exemptions, to withhold tax upon the sale of Shares at a rate of 25% of the consideration for individuals and corporations.

Upon the sale of traded securities, a detailed return, including a computation of the tax due, must be filed and an advance payment must be paid to the Israeli Tax Authority on January 31 and July 31 of every tax year in respect of sales of traded securities made within the previous six months. However, if all tax due was withheld at source according to applicable provisions of the Israeli Income Tax Ordinance and regulations promulgated thereunder, the aforementioned return need not be filed, provided

that (among other conditions) (i) such income was not generated from business conducted in Israel by the taxpayer, (ii) the taxpayer has no other taxable sources of income in Israel with respect to which a tax return is required to be filed and an advance payment does not need to be made, and (iii) the taxpayer is not obligated to pay Excess Tax (as further explained below). Capital gains are also reportable on annual income tax returns.

***Exercise of Warrants and Certain Adjustments to the Warrants***

Investors will generally not recognize gain or loss for Israeli tax purposes on the exercise of a Warrant and related receipt of an ordinary share (unless, for instance, cash is received in lieu of the issuance of a fractional ordinary share). Nevertheless, the Israeli income tax treatment and the tax consequences of a cashless exercise of Warrants into Ordinary Shares is unclear. Furthermore, the exercise terms of the Warrants may be adjusted in certain circumstances. An adjustment to the number of Ordinary Shares that will be issued on the exercise of the Warrants or an adjustment to the exercise price of a Warrant may be treated as a taxable event under Israeli tax law even if such holder does not receive any cash or other property in connection with the adjustment. Investors should consult their tax advisors regarding the proper treatment of any exercise of and/or adjustments to the Warrants.

***Dividends***

Dividends distributed by a company to a shareholder who is an Israeli resident individual will generally be subject to income tax at a rate of 25%. However, a 30% tax rate will apply if the dividend recipient is a Controlling Shareholder, as defined above, at the time of distribution or at any time during the preceding 12-month period. If the recipient of the dividend is an Israeli resident corporation, such dividend will generally be exempt from Israeli income tax provided that the income from which such dividend is distributed, derived or accrued within Israel.

Dividends distributed by an Israeli resident company to a non-Israeli resident (either an individual or a corporation) are generally subject to Israeli withholding tax on the receipt of such dividends at the rate of 25% (30% if the dividend recipient is a Controlling Shareholder at the time of distribution or at any time during the preceding 12-month period). These rates may be reduced under the provisions of an applicable double tax treaty. For example, under the U.S.-Israel Double Tax Treaty, the following withholding tax rates will apply in respect of dividends distributed by an Israeli resident company to a U.S. resident: (i) if the U.S. resident is a corporation that holds during that portion of the taxable year which precedes the date of payment of the dividend and during the whole of its prior taxable year (if any), at least 10% of the outstanding shares of the voting share capital of the Israeli resident paying corporation and not more than 25% of the gross income of the Israeli resident paying corporation for such prior taxable year (if any) consists of certain types of interest or dividends the tax rate is 12.5%; (ii) if both the conditions mentioned in clause (i) above are met and the dividend is paid from an Israeli resident company's income which was entitled to a reduced tax rate under The Law for the Encouragement of Capital Investments, 1959, the tax rate is 15%; and (iii) in all other cases, the tax rate is 25%. The aforementioned rates under the U.S.-Israel Double Tax Treaty will not apply if the dividend income is attributed to a permanent establishment of the U.S. resident in Israel.

***Excess Tax***

Individual holders who are subject to tax in Israel (whether any such individual is an Israeli resident or non-Israeli resident) and who have taxable income that exceeds a certain threshold in a tax year (721,560 NIS for 2024, linked to the Israeli Consumer Price Index) will be subject to an additional tax at the rate of 3% on his or her taxable income for such tax year that is in excess of such amount. For this purpose, taxable income including, but not limited to, taxable capital gain from the sale of securities and taxable income from interest and dividends, subject to the provisions of an applicable double tax treaty.

***Estate and Gift Tax***

Israel does not currently impose estate or gift taxes if the Israeli Tax Authority is satisfied that the gift was made in good faith and on condition that the recipient of the gift is not a non-Israeli resident.

***Foreign Exchange Regulations***

Non-residents of Israel who hold our Shares are able to receive any dividends, and any amounts payable upon the dissolution, liquidation and winding up of our affairs, repayable in non-Israeli currency at the rate of exchange prevailing at the time of conversion. However, Israeli income tax is generally required to have been paid or withheld on these amounts. In addition, the statutory framework for the potential imposition of currency exchange control has not been eliminated and may be restored at any time by administrative action.

**F. Dividends and Paying Agents**

Not applicable.

**G. Statement by Experts**

Not applicable.

**H. Documents on Display**

We are subject to the information reporting requirements of the Exchange Act that are applicable to foreign private issuers, and under those requirements will file reports with the SEC through its electronic data gathering, analysis and retrieval (EDGAR) system. Our securities filings, including this Annual Report and the exhibits thereto, are available electronically through the SEC website (*http://www.sec.gov*).

As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. Furthermore, as a foreign private issuer, we are also not subject to the requirements of Regulation FD (Fair Disclosure) promulgated under the Exchange Act. In addition, we will not be required under the Exchange Act to file annual or other 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 maintain a corporate website at *www.Scinai.com.* Information contained on, or that can be accessed through, our website does not constitute a part of this annual report. We have included our website address in this annual report solely as an inactive textual reference.

**I. Subsidiary Information**

Not applicable.

**Item 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position, results of operations or cash flows due to adverse changes in financial market prices and rates, including interest rates and foreign exchange rates, of financial instruments. Our market risk exposure is primarily a result of interest rates and foreign currency exchange rates.

***Interest Rate Risk***

Following the date of this annual report, we do not anticipate undertaking any significant long-term borrowings. At present, our investments consist primarily of cash and cash equivalents and financial assets at fair value.

Following the date of this annual report, we may invest in investment-grade marketable securities with maturities of up to three years, including commercial paper, money market funds, and government/non-government debt securities. The primary objective of our investment activities is to preserve principal while maximizing the income that we receive from our investments without significantly increasing risk and loss. Our investments are exposed to market risk due to fluctuation in

interest rates, which may affect our interest income and the fair market value of our investments, if any. We manage this exposure by performing ongoing evaluations of our investments. Due to the short-term maturities, if any, of our investments to date, their carrying value has always approximated their fair value. If we decide to invest in investments other than cash and cash equivalents, it will be our policy to hold such investments to maturity in order to limit our exposure to interest rate fluctuations.

***Foreign Currency Exchange Risk***

Our foreign currency exposures give rise to market risk associated with exchange rate movements of the U.S. dollar, our functional and reporting currency, mainly against the NIS and the Euro. Although the U.S. dollar is our functional currency, a significate portion of our expenses are denominated in both NIS and Euro. Our NIS and Euro expenses consist principally of payments made to our partners at MPG and UMG, sub-contractors and consultants for pre-clinical trials and other research and development activities as well as payments made to purchase new equipment. We anticipate that a sizable portion of our expenses will continue to be denominated in currencies other than the NIS. If the US. dollar fluctuates significantly against either the NIS or the Euro, it may have a negative impact on our results of operations. To date, fluctuations in the exchange rates have not materially affected our results of operations or financial condition for the periods under review.

**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**

The Bank of New York Mellon acts as depositary, for our American Depositary Shares, also referred to as ADSs which trade on the Nasdaq Capital Market. Each ADS represents four hundred (400) ordinary shares (or a right to receive four hundred (400) ordinary shares). Each ADS also represents any other securities, cash or other property which may be held by the depositary. The Bank of New York Mellon's principal executive office is located at One Wall Street, New York, New York 10286.

**Fees and Expenses**

| ***Persons depositing or withdrawing ordinary shares or ADS holders must pay*:** | ***For*:** |
|---|---|
| $5.00 (or less) per 100 ADSs (or portion of 100 ADSs) | ● Issuance of ADSs, including issuances resulting from a distribution of ordinary shares or rights or other property Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates |
| $.05 (or less) per ADS | ● Any cash distribution to ADS holders |
| A fee equivalent to the fee that would be payable if securities distributed to you had been ordinary shares and the ordinary shares had been deposited for issuance of ADSs | ● Distribution of securities distributed to holders of deposited securities which are distributed by the depositary to ADS holders |
| $.05 (or less) per ADS per calendar year | ● Depositary services |
| Registration or transfer fees | ● Transfer and registration of ordinary shares on our share register to or from the |

| | |
|---|---|
| Expenses of the depositary | name of the depositary or its agent when you deposit or withdraw ordinary shares<br>● Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement) Converting foreign currency to U.S. dollars |
| Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or ordinary shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes | ● As necessary |
| Any charges incurred by the depositary or its agents for servicing the deposited securities | ● As necessary |

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing ordinary shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse and/or share revenue from the fees collected from ADS holders, or waive fees and expenses for services provided, generally relating to costs and expenses arising out of establishment and maintenance of the ADS program. In performing its duties under the deposit agreement, the depositary may use brokers, dealers or other service providers that are affiliates of the depositary and that may earn or share fees or commissions.

## PART II

### Item 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

### Item 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

Not applicable

### Item 15. CONTROLS AND PROCEDURES

**Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2023 (the "Evaluation Date"). Based on such evaluation, those officers have concluded that, as of the Evaluation Date, our disclosure controls and procedures were effective.

**Management Annual Report on Internal Control over Financial Reporting**

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

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and disposition of our assets;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and

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

Our management, including the CEO and CFO, conducted an evaluation, pursuant to Rule 13a-15(c) promulgated under the Exchange Act, of the effectiveness, as of the end of the period covered by this Annual Report, of its internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control - Integrated Framework (2013). Based on the results of this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2023.

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**Changes in Internal Control Over Financial Reporting**

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There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

During the year ended December 31, 2023, we implemented certain internal control procedures to address the previously identified material weaknesses related to our control environment, risk assessment and monitoring.

The Company's management is also responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a set of processes designed by, or under the supervision of, a company's principal executive designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

The Company's internal control over financial reporting includes those policies and procedures that:

1. Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;

2. Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of the Company's management and directors; and

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. It should be noted that any system of internal control, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system will be met. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

**Item 16. [Reserved]**

**Item 16A. AUDIT COMMITTEE FINANCIAL EXPERT**

Our Board of Directors has determined that Mr. Adi Raviv, a member of our Audit Committee, is an audit committee financial expert, as defined under the rules under the Exchange Act, and is independent in accordance with applicable Exchange Act rules and NASDAQ rules.

**Item 16B. CODE OF ETHICS**

We have adopted a written code of ethics that applies to our officers and employees, including our principal executive officer, principal financial officer, principal controller and persons performing similar functions as well as our directors. Our Code of Business Conduct and Ethics is posted on our website at *www.Scinai.com*. Information contained on, or that can be accessed through, our website does not constitute a part of this annual report on Form 20-F and is not incorporated by reference herein. If we make any amendment to the Code of Business Conduct and Ethics or grant any waivers, including any implicit waiver, from a provision of the code, we will disclose the nature of such amendment or waiver on our website to the extent required by the rules and regulations of the SEC including the instructions to Item 16B of Form 20-F. We have not granted any waivers under our Code of Business Conduct and Ethics.

**Item 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

**Principal Accountant Fees and Services**

Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global ("EY Israel"), a member of Ernst & Young Global, an independent registered public accounting firm, served as our independent registered public accountants until August 24, 2024. At such time, Kesselman & Kesselman, certified public accountants in Israel and a member of PricewaterhouseCoopers International Limited ("PwC Israel"), became our independent registered public accountants.

We paid the following fees for professional services rendered by PwC Israel, for the year ended December 31, 2023 and rendered by EY Israel for the year ended December 31, 2022:

| | 2023 | 2022 |
|---|---|---|
| | (in thousands of U.S. dollars) | |
| Audit Fees | $ 136 | $ 126 |
| Audit-Related Fees | $ 51 | $ 49 |
| Additional fees | $ - | $ 50 |
| **Total** | $ 187 | $ 225 |

"**Audit fees**" are the aggregate fees paid for the audit of our annual financial statements. This category also includes services that generally the independent accountant provides, such as consents and assistance with and review of documents filed with the SEC.

"**Audit-related fees**" are the aggregate fees paid for assurance and related services that are reasonably related to the performance of the audit and are not reported under audit fees. These fees primarily include accounting consultations regarding the accounting treatment of matters that occur in the regular course of business, implications of new accounting pronouncements and other accounting issues that occur from time to time.

"**Additional fees**" include fees for professional services rendered by our independent registered public accounting firm for tax compliance, transfer pricing, tax advice on actual or contemplated transactions and Israel innovation authority advisory.

**Audit Committee's Pre-approval Policies and Procedures**

Our audit committee has a pre-approval policy for the engagement of our independent accountant to perform certain audit and non-audit services. Pursuant to this policy, which is designed to assure that such engagements do not impair the independence of our auditors, the audit committee pre-approves annually a catalog of specific audit and non-audit services in the categories of audit service, audit-related service and tax services that may be performed by our independent accountants.

**Item 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES**

Not applicable.

**Item 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS**

Not applicable.

**Item 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT**

(a) In [May and June 2023], the Audit Committee of the Board of Directors of Scinai Immunotherapeutics Ltd. (the "Company") conducted a process to select a firm to serve as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2023, and for an additional period until the next annual general meeting of our shareholders. The Audit Committee invited a number of firms to participate in this process and following such process the Audit Committee recommended to the Board of Directors that, subject to the approval of the shareholders at the Company's next annual general meeting of shareholders (the "Meeting"), the Company appoint Kesselman & Kesselman, certified public accountants in Israel and a member of PricewaterhouseCoopers International Limited ("PwC Israel"). In conjunction with the recommendation of PwC Israel to serve as the Company's independent registered public accounting firm, and subject to the approval of the Company's shareholders at the Meeting, the engagement of the Company's current independent registered public accounting year, Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global ("EY Israel"), concluded at the end of the Meeting, which was held on August 24, 2023.

EY Israel's reports on the Company's consolidated financial statements as of and for the years ended December 31, 2022 and 2021 did not contain an adverse opinion or a disclaimer of opinion, and were not qualified or modified as to uncertainty, audit scope, or accounting principles.

EY Israel served as our independent registered public accountants for the years ended December 31, 2022, and 2021. During such period and until the Meeting, there were (i) no disagreements between the Company and EY Israel on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements were not resolved to the satisfaction of EY Israel and which, if not resolved to the satisfaction of EY Israel, would have caused EY Israel to make reference to the subject matter of the disagreement in their reports on the Company's consolidated financial statements for such years, and (ii) no "reportable events" as that term is defined in Item 16(a)(1)(v) of Form 20-F

The Company provided EY Israel with a copy of the disclosures made by the Company under this Item 16F) and requested that EY Israel furnish the Company with a letter addressed to the Securities and Exchange Commission stating whether EY Israel agrees with the statements made by the Company in this Item 16F and, if not, stating the respects in which EY Israel does not agree. A copy of EY Israel's letter is filed as Exhibit 16.1 to this Annual Report.

The appointment of PwC as the Company's independent registered public accounting firm was effective on August 24, 2023, following the Audit Committee's recommendation and the Meeting which approved such appointment.

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During the Company's two most recent fiscal years ended December 31, 2022 and December 31, 2021, and the subsequent interim period through August 24, 2023, neither the Company nor anyone acting on its behalf consulted with PwC Israel regarding (i) the application of accounting principles to a specified transaction, either completed or proposed; (ii) the type of audit opinion that might be rendered on the Company's financial statements and neither a written report nor oral advice was provided to the Company that PwC Israel concluded was an important factor considered by the Company in reaching a decision as to any accounting, auditing or financial reporting issue; or (iii) any matter that was either the subject of a disagreement (as described in Item 16(a)(1)(iv) of Form 20-F and the related instructions) or a reportable event (as described in Item 16(a)(1)(v) of Form 20-F).

**Item 16G. CORPORATE GOVERNANCE**

Companies incorporated under the laws of the State of Israel whose shares are publicly traded, including companies with shares listed on the NASDAQ Capital Market, are considered public companies under Israeli law and are required to comply with various corporate governance requirements under Israeli law relating to such matters as the audit committee, the compensation committee and an internal auditor. These requirements are in addition to the corporate governance requirements imposed by the listing rules of the NASDAQ Capital Market and other applicable provisions of U.S. securities laws to which we are subject to (as a foreign private issuer) since the closing of the offering in the U.S. and the listing of the ADSs and warrants on the NASDAQ Capital Market. Under the listing rules of the NASDAQ Capital Market, a foreign private issuer, such as us, may generally follow its home country rules of corporate governance in lieu of the comparable requirements of the listing rules of the NASDAQ Capital Market, except for certain matters including (among others) the composition and responsibilities of the audit committee and the independence of its members within the meaning of the rules and regulations of the SEC.

**NASDAQ Capital Market listing rules and Home Country Practices**

In accordance with Israeli law and practice, and subject to the exemption set forth in Rule 5615 of the listing rules of the NASDAQ Capital Market, we intend to follow the provisions of the Companies Law, rather than the listing rules of the NASDAQ Capital Market, with respect to the following requirements:

*Distribution of certain reports to shareholders.* As opposed to the listing rules of the NASDAQ Capital Market, which require listed issuers to make certain reports, such as annual reports, interim reports and quarterly reports, available to shareholders in one of a number of specific manners, Israeli law does not require us to distribute periodic reports directly to shareholders, and the generally accepted business practice in Israel is not to distribute such reports to shareholders, but to make such reports available through a public website. In addition to making such reports available on a public website, we plan to make our audited financial statements available to our shareholders at our offices and will only mail such reports to shareholders upon request. As a foreign private issuer, we are generally exempt from the SEC's proxy solicitation rules.

*Compensation of officers.* We follow the provisions of the Companies Law with respect to matters in connection with the responsibilities of our compensation committee, office holder compensation and any required approval by the shareholders of such compensation. Israeli law and our articles of association do not require that the independent members of our board of directors, or a compensation committee composed solely of independent members of our board of directors, determine an executive officer's compensation, as is generally required under the listing rules of the NASDAQ Capital Market with respect to the Chief Executive Officer and all other executive officers of a company. Our compensation committee has been established and conducts itself in accordance with the provisions governing the responsibilities of a compensation committee as set forth in the Companies Law. Furthermore, compensation of office holders is determined and approved by our compensation committee, and in general, by our board of directors as well, and in certain circumstances by our shareholders, as detailed below under the caption "—Shareholder Approval." Thus, we will seek shareholder approval for all corporate actions with respect to office holder compensation (including the compensation required to be approved for our Chief Executive Officer) requiring such approval under the requirements of the Companies Law, including seeking prior approval of the shareholders for the compensation policy and for certain office holder compensation, rather than seeking approval for such

corporate actions in accordance with listing rules of the NASDAQ Capital Market. See "— Compensation Committee and Compensation Policy" below.

*Compensation Committee*. Pursuant to the Companies Law, we established a compensation committee as detailed below. Since the consummation of the offering, our board of directors has affirmatively determined that each member of our compensation committee qualifies as "independent" under applicable NASDAQ Capital Market and SEC rules.

*Annual Shareholders Meeting.* The Company shall convene an annual shareholders meeting under the requirements (including required dates) of the Companies Law, rather than as required under rule NASDAQ Capital Market Rule 5620(a).

*Shareholder approval*. We will seek shareholder approval for all corporate actions requiring such approval under the requirements of the Companies Law, rather than seeking approval for corporate actions in accordance with NASDAQ Capital Market Listing Rule 5635. In particular, under this NASDAQ Capital Market rule, shareholder approval is generally required for: (i) an acquisition of shares or assets of another company that involves the issuance of 20% or more of the acquirer's shares or voting rights or if a director, officer or 5% shareholder has greater than a 5% interest in the target company or the consideration to be received; (ii) the issuance of shares leading to a change of control; (iii) adoption or amendment of equity compensation arrangements; and (iv) issuances of 20% or more of the shares or voting rights (including securities convertible into, or exercisable for, equity) of a listed company via a private placement (or via sales by directors, officers or 5% shareholders) if such equity is issued (or sold) at below the greater of the book or market value of shares. By contrast, under the Companies Law, shareholder approval is required for, among other things: (a) transactions with directors concerning the terms of their service or indemnification, exemption and insurance for their service (or for any other position that they may hold at a company), for which approvals of the compensation committee, board of directors and shareholders are all required, (b) extraordinary transactions with controlling shareholders of publicly held companies, which require the special approval described below under "Disclosure of personal interests of controlling shareholders and approval of certain transactions," (c) terms of office and employment or other engagement of our controlling shareholder, if any, or such controlling shareholder's relative, which require the special approval described below under "Disclosure of personal interests of controlling shareholders and approval of certain transactions, (d) approval of transactions with Company's Chief Executive Officer with respect to his or hers compensation, whether in accordance with the approved compensation policy of the Company or not in accordance with the approved compensation policy of the Company, or transactions with officers of the Company not in accordance with the approved compensation policy, and (e) approval of the compensation policy of the Company for office holders. In addition, under the Companies Law, a merger requires approval of the shareholders of each of the merging companies. See also "Description of Share Capital — Acquisitions under Israeli Law — Merger" below.

*Quorum for shareholder meetings*. As permitted under the Companies Law, pursuant to our articles of association, the quorum required for an ordinary meeting of shareholders will consist of one or more shareholders present in person, by proxy or by other voting instrument in accordance with the Companies Law, who hold, in the aggregate, at least 10% of the voting power of our shares (or, for so long we do not qualify as a foreign private issuer and for only so long as required by the Nasdaq Stock Market, 33 1/3% of our outstanding ordinary shares), (and in an adjourned meeting, any number of shareholders), instead of 33 1/3% of the issued share capital required under the NASDAQ Capital Market corporate governance rules.

Other than the foregoing home country practices, we otherwise intend to comply with the rules generally applicable to U.S. domestic companies listed on the NASDAQ Capital Market. We may in the future decide to use the foreign private issuer exemption with respect to some or all of the other NASDAQ Capital Market corporate governance rules. Following our home country corporate governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on the NASDAQ Capital Market may provide less protection to you than what is accorded to investors under the listing rules of the NASDAQ Capital Market applicable to domestic U.S. issuers.

**Item 16H. MINE SAFETY DISCLOSURE**

Not applicable.

**Item 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS**

Not applicable.

**ITEM 16J. INSIDER TRADING POLICIES**

Pursuant to applicable SEC transition guidance, the disclosure required by Item 16J will only be applicable to the Company from the fiscal year ending on December 31, 2024.

**ITEM 16K. CYBERSECURITY**

We operate in the biotechnology sector, which is subject to various cybersecurity risks that could adversely affect our business. We recognize the critical importance of developing, implementing, and maintaining cybersecurity measures to safeguard our information systems and protect the confidentiality, integrity, and availability of our data. We currently have security measures in place to protect and prevent data loss and other security breaches, including a cybersecurity risk assessment program. Our network infrastructure was designed with cybersecurity in mind, incorporating a range of critical components such as firewalls, intrusion detection and prevention systems, virtual private networks (VPNs), and secure Wi-Fi access points. Additionally, strong authentication mechanisms, encryption protocols, and robust monitoring tools are essential elements for ensuring a secure network infrastructure. These components work together to protect against unauthorized access, data breaches, malware attacks, and other cybersecurity threats.

Our current cybersecurity risk assessment program consists of routine evaluations of our network infrastructure, penetration testing and continuous monitoring of security controls and threats. The program outlines governance, policies and procedures, and technology we use to oversee and identify risks from cybersecurity threats and is informed by previous cybersecurity incidents we have observed within the Company..

Our COO and Quality Unit Manager are responsible for day-to-day assessment and management of risks from cybersecurity threats, including the prevention, mitigation, detection, and remediation of cybersecurity incidents. Our COO is experienced in operating a company which offers cybersecurity services. Our COO and Quality Unit Manager are informed of cybersecurity risks or incidents by our IT manager who regularly monitors our systems to detect cybersecurity incidents or risks.

The Board of Directors is responsible for oversight of risks from cybersecurity threats in conjunction with management. The Board of Directors receives reports and updates from management with respect to the management of risks from cybersecurity threats. Such reports cover the Company's information technology security program, including its current status, capabilities, objectives and plans, as well as the evolving cybersecurity threat landscape. The Board of Directors takes into consideration such reports and updates into its overall risk assessment of the Company.

We leverage the advice of third-party consultants to help us assess and identify risks from cybersecurity threats, including the threat of a cybersecurity incident, and manage our risk assessment program. Among other things, these third-party consultants conduct security audits, penetration testing, and vulnerability assessments to evaluate the strength of our defenses. They also offer expertise in regulatory compliance, helping us ensure that our security measures align with industry standards and legal requirements. Additionally, they provide ongoing monitoring and analysis of emerging threats, allowing us to proactively adapt and strengthen our cybersecurity posture.[1]

We also have policies and procedures to oversee and identify the risks from cybersecurity threats associated with our use of third-party service providers. When engaging with vendors or partners, we

[1] Describe role of the third-party assessors, consultants, auditors, etc., within the Company's processes for assessing, identifying, and managing material risks from cybersecurity threats discussed above.

prioritize those who demonstrate robust cybersecurity measures and a strong commitment to protecting sensitive data. To mitigate risks associated with third-party providers, we incorporate specific cybersecurity requirements into contracts and service level agreements. These agreements outline expectations regarding data protection, access controls, incident reporting, and compliance monitoring. Furthermore, we implement other mechanisms to enhance security when working with third-party providers, including implementing two-factor authentication. By implementing these measures, we aim to minimize the cybersecurity risks associated with third-party service providers and ensure the protection of our organization's assets and data.

To date, no cybersecurity incident (or aggregation of incidents) or cybersecurity threat has materially affected our results of operations or financial condition. For information on how a cybersecurity threat might affect us, see also *Item 3D. Risk Factors – General Risk Factors*.

## PART III

### Item 17. FINANCIAL STATEMENTS

The Registrant has responded to Item 18 in lieu of responding to this Item.

### Item 18. FINANCIAL STATEMENTS

See the financial statements beginning on page F-1. The following financial statements and financial statement schedules are filed as part of this Annual Report on Form 20-F together with the report of the independent registered public accounting firm:

### Item 19. EXHIBITS

**EXHIBIT INDEX**

| Exhibit No. | Exhibit Description |
|---|---|
| 1.1 | Articles of Association of Scinai Immunotherapeutics Ltd., incorporated by reference to Exhibit 3.1 to the Registration Statement on Form F-1 filed with the SEC on October 30 , 2023. |
| 2.1 | Form of Deposit Agreement between the Company Ltd., The Bank of New York Mellon as Depositary, and owners and holders from time to time of ADSs issued thereunder, incorporated by reference to Exhibit 4.1 to the Registration Statement on Form F-1 filed with the SEC on April 6, 2015. |
| 2.2 | Specimen American Depositary Receipt (included in Exhibit 2.1). |
| 2.3* | Description of Share Capital. |
| 2.4 | Form of Pre-Funded Warrant, incorporated by reference to Exhibit 4.16 to the Registration Statement on Form F-1/A filed with the SEC on December 14, 2022. |
| 2.5 | Form of Exchangeable Warrant, incorporated by reference to the Registration Statement on Form F-1/A filed with the SEC on December 14, 2022. |
| 2.6 | Form of Non-Exchangeable Warrant, incorporated by reference to the Registration Statement on Form F-1/A filed with the SEC on December 14, 2022. |
| 2.7 | Form of Warrant, incorporated by reference to Exhibit 1.3 to Form 6-K submitted with the SEC on September 19, 2023. |
| 2.8 | Form of Pre-Funded Warrant, incorporated by reference to Exhibit 1.2 to Form 6-K submitted with the SEC on September 19, 2023. |
| 2.9 | Form of Placement Agent Warrant, incorporated by reference to Exhibit 1.4 to Form 6-K filed with the SEC on September 19, 2023. |
| 4.1 | 2005 Share Incentive Plan, incorporated by reference to Exhibit 4.1 to the Annual Report on Form 20-F filed with the SEC on June 12, 2020. |
| 4.2 | 2018 Share Incentive Plan, incorporated by reference to Exhibit 4.2 to the Annual Report on Form 20-F filed with the SEC on June 12, 2020. |
| 4.3 | Compensation Policy, incorporated by reference to Appendix B to the Exhibit 99.1 to the Form 6-K filed with the SEC on November 22, 2021. |

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| 4.4 | Employment Agreement dated January 20, 2021, between the Company and Mr. Amir Reichman. |
| 4.5 | Employment Agreement dated March 15, 2005, between the Company and Dr. Tamar Ben-Yedidia, incorporated by reference to Exhibit 10.6 to the Registration Statement on Form F-1 filed with the SEC on December 29, 2014. |
| 4.6 | Addendum to Employment Agreement dated April 1, 2012, between the Company and Dr. Tamar-Ben Yedidia, incorporated by reference to Exhibit 10.11 to the Registration Statement on Form F-1 filed with the SEC on December 29, 2014. |
| 4.7 | Addendum to Employment Agreement dated May 28, 2015, between the Company and Dr. Tamar-Ben Yedidia incorporated by reference to Exhibit 10.8 to the Annual Report on form 10-K filed with the SEC on April 17, 2023. |
| 4.8 | Addendum to Employment Agreement dated August 15, 2018, between the Company. and Dr. Tamar-Ben Yedidia, incorporated by reference to Exhibit 10.9 to the Annual Report on form 10-K filed with the SEC on April 17, 2023. |
| 4.9 | Employment Agreement dated September 5, 2018, between the Company and Elad Mark, incorporated by reference to Exhibit 10.10 to the Annual Report on form 10-K filed with the SEC on April 17, 2023. |
| 4.10 | Form of Indemnification Letter (unofficial English translation from Hebrew original), incorporated by reference to Exhibit 10.9 to the Registration Statement on Form F-1 filed with the SEC on December 29, 2014. |
| 4.11 | Form of Indemnification and Exculpation Agreement, incorporated by reference to Exhibit 10.18 to the Registration Statement on Form F-1 filed with the SEC on April 6, 2015. |
| 4.12 | Finance Contract between the Company and the European Investment Bank, incorporated by reference to Exhibit 99.2 to Form 6-K filed with the SEC on June 19, 2017. |
| 4.13 | Amendment No. 1, dated January 11, 2021, to Finance Contract dated June 19, 2017, by and between the Company and the European Investment Bank, incorporated by reference to Exhibit 4.16 to the Annual Report on Form 20-filed with the SEC on May 13, 2021. |
| 4.14 | Lease agreement dated July 10, 2017 between the Company and Unihad BioPark Ltd., incorporated by reference to Exhibit 4.19 to the Form 20-F filed with the SEC on April 30, 2018. |
| 4.15 | Services Agreement between the Company and Mark Germain, incorporated by reference to Appendix C to the Form 6-K filed with the SEC on April 23, 2019. |
| 4.16+ | License Agreement, dated December 11, 2021, between the Company and Max-Planck-Innovation GmbH, incorporated by reference to Exhibit 4.16 to the Annual Report on Form 20-F filed with the SEC on March 28, 2022. |
| 4.17+ | Accompanying Research Collaboration Agreement, dated December 11, 2021, between the Company, Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V and Georg-August-Universität Göttingen Stiftung Öffentlichen Rechts Universitätsmedizin Göttingen, incorporated by reference to Exhibit 4.17 to the Annual Report on Form 20-F filed with the SEC on March 28, 2022. |
| 4.18 + | Research Collaboration Agreement, dated March 23, 2022, between the Company Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V and Georg-August-Universität Göttingen Stiftung Öffentlichen Rechts Universitätsmedizin Göttingen, incorporated by reference to Exhibit 4.18 to the Annual Report on Form 20-F filed with the SEC on March 28, 2022. |

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|---|---|
| 4.19 + | Form of License Agreement between the Company, Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V and Georg-August-Universität Göttingen Stiftung Öffentlichen Rechts Universitätsmedizin Göttingen, incorporated by reference to Exhibit 10.21 to the Annual Report on form 10-K filed with the SEC on April 17, 2023. |
| 4.20 | Form of Securities Purchase Agreement, incorporated by reference to Exhibit 1.1 to Form 6-K submitted with the SEC on September 19, 2023. |
| 4.21 | Amendment Agreement dated August 9, 2022, to Finance Contract dated June 19, 2017 and as amended from time to time, by and between the Company and the European Investment Bank, incorporated by reference to Exhibit 10.21 to the Registration Statement on Form F-1 f filed with the SEC on October 30, 2023, |
| 10.1* | Consent of Kost Forer Gabbay & Kasierer, Certified Public Accountant (Isr.), a member of Ernst & Young Global, independent registered public accounting firm for the Registrant |
| 10.2* | |
| 11 | Code of Conduct , incorporated by reference to Exhibit 14.1 to the Annual Report on form 10-K filed with the SEC on April 17, 2023. |
| 12.1* | Certification of the Chief Executive Officer pursuant to rule 13a-14(a) of the Securities Exchange Act of 1934. |
| 12.2* | Certification of the Chief Financial Officer pursuant to rule 13a-14(a) of the Securities Exchange Act of 1934. |
| 13.1* | Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, furnished herewith. |
| 13.2* | Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, furnished herewith. |
| 16.1* | Letter, from Kost Forer Gabbay & Kasierer, Certified Public Accountant (Isr.), a member of Ernst & Young Global, to the Secuurities and Exchange Commission, dated, [____], 2024. |
| 97.1* | Scinai Immunotherapeutics Policy for Recovery of Erroneously Awarded Compensation |

* Filed herewith.

\+ Certain confidential portions of this exhibit have been redacted from the publicly filed document because such portions are (i) not material and (ii) would be competitively harmful if publicly disclosed.

**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.

**Scinai Immunotherapeutics Ltd.**

Date: May 15[—], 2024

By: /s/ Amir Reichman
Amir Reichman
Chief Executive Officer

**Commented [AR82]:** @Perry Wildes need to fill in the date of filing

**Commented [PW83R82]:** done