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**

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: Not applicable

For the transition period from ____ to _____

Commission file number 001-35948

Kamada Ltd.

(Exact name of registrant as specified in its charter)

N/A
(Translation of Registrant's name into English)

State of Israel
(Jurisdiction of incorporation or organization)

2 Holzman St.
Science Park
P.O Box 4081
Rehovot 7670402
Israel
(Address of principal executive offices)

Amir London, Chief Executive Officer
2 Holzman St., Science Park
Rehovot 7670402, Israel
+972 8 9406472
(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	Name of Each Exchange on which Registered
Ordinary Shares, par value NIS 1.00 each	KMDA	The Nasdaq Stock Market LLC

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

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

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

As of December 31, 2023, the Registrant had 57,479,528 Ordinary Shares outstanding.

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 definition 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.

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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In this Annual Report on Form 20-F (this "Annual Report"), unless the context indicates otherwise, references to "NIS" are to the legal currency of Israel, "U.S. dollars," "$" or "dollars" are to United States dollars, and the terms "we", "us", the "Company", "our company", "our", and "Kamada" refer to Kamada Ltd., along with its consolidated subsidiaries.

This Annual Report contains forward-looking statements that relate to future events or our future financial performance, which express the current beliefs and expectations of our management in light of the information currently available to it. Such statements involve a number of known and unknown risks, uncertainties and other factors that could cause our actual future results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied by such forward-looking statements. Forward-looking statements include all statements that are not historical facts and can be identified by words such as, but without limitation, "believe", "expect", "anticipate", "estimate", "intend", "plan", "target", "likely", "may", "will", "would", or "could", or other words, expressions or phrases of similar substance or the negative thereof. We have based these forward-looking statements largely on our management's current expectations and future events and financial trends that we believe may affect our financial condition, results of operation, business strategy and financial needs. Forward-looking statements include, but are not limited to, statements about:

- *our continued focus on driving profitable growth through expanding our growth catalysts, which include: investment in the commercialization and life cycle management of our commercial Proprietary products led by KEDRAB and CYTOGAM sales in the U.S. market; continue growing our Proprietary hyper-immune portfolio's revenues in existing and new geographic markets through registration and launch of the products in new territories; expanding sales of GLASSIA in ex-U.S. markets; generating royalties from GLASSIA sales by Takeda Pharmaceuticals Company Limited ("Takeda"); expanding our plasma collection capabilities in support of our growing demand for hyper-immune specialty plasma as well as sales of normal source plasma to the market; exploring strategic business development opportunities to identify potential acquisitions or in-licensing targeted products synergistic to our existing commercial activities that could be added to our proprietary products portfolio; continued increase of our Distribution segment revenues specifically through launching the eleven biosimilar products in Israel; and leveraging our U.S. Food and Drug Administration ("FDA")-approved hyperimmune immunoglobulins ("IgG") platform technology, manufacturing, research and development expertise to advance development and commercialization of additional product candidates, including our Inhaled Alpha-1 antitrypsin ("AAT") product candidate and identify potential commercial partners for this product;*

- *our current expectation to generate total revenues for the fiscal year 2024 in the range of $156 million to $160 million and adjusted EBITDA in the range of $27 million to $30 million. The projected 2024 revenue and adjusted EBITDA forecast represents double digit growth over fiscal year 2023 (for details regarding the use of non-IFRS measures, see "Item 5. Operating and Financial Review and Prospectus—Non-IFRS Financial Measures");*

- *our belief that sales of KEDRAB and CYTGOM will continue to increase in the coming years and will be a major growth catalyst for the foreseeable future;*

- *our expectation that based on current GLASSIA sales and forecasted future growth, we will receive royalties from Takeda in the range of $10 million to $20 million per year for 2024 to 2040;*

- *our expectation to continue the supply of CYTOGAM, HEPAGAM, VARIZIG and WINRHO SDF to Canadian Blood Services (CBS) for an additional two years out of the total three-year agreement, which commenced on April 1, 2023, for an approximate total value of $22 million, of which an aggregate of $6.4 million of such products were sold to CBS in 2023;*

- *our expectation to continue manufacturing HEPAGAM B, VARIZIG and WINRHO SDF at Emergent BioSolutions Inc. ("Emergent") in the foreseeable future, and, upon decision to do so, initiate in parallel a technology transfer project for transitioning the manufacturing of these products to our manufacturing facility in Beit Kama, Israel, subject to executing a new amended manufacturing services agreement with Emergent covering operational aspects and the technology transfer related services and scope, and our anticipation that if initiated, such a technology transfer may be completed within four to five years following initiation thereof;*

- *our intention to expand our Proprietary plasma-derived products business, includi*ng that of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF, by *leveraging our existing strong international distribution network to grow our commercial revenue in the existing markets in which we sell our products, as well as to expand to geographic markets in which these products are not currently sold;*

- *our expectation that, subject to European Medicines Agency ("EMA") and subsequently the Israeli Ministry of Health* ("*IMOH") approvals, we will launch in Israel eleven biosimilar products through 2028 and that sales generated by the launch of the biosimilar products portfolio will become a major growth catalyst, and our estimate that the potential aggregate peak revenues, achievable within several years of launch, generated by the distribution of all eleven biosimilar products, will be in the range of approximately $30 million to $34 million annually;*

- *our ability to procure adequate quantities of plasma and fraction IV from our suppliers, which are acceptable for use in our manufacturing processes;*

- *our intention to leverage our experience with plasma collection to establish additional plasma collection centers in the United States with the intention of collecting normal source plasma to be sold for manufacturing by third parties, as well as hyper-immune specialty plasma required for manufacturing of our proprietary products; our expectation to commence operations at our new plasma collection center in Uvalde, Texas during 2024, following the completion of its construction and obtaining the required regulatory approvals, and to lease a subsequent facility and initiate construction activities to establish our third plasma collection center during early 2024; and our expectation that the expansion of our plasma collection capabilities will allow us to better support our plasma needs as well as generate additional revenues through sales of collected normal source plasma;*

- *our intention to seek new long-term supply agreements for hyper-immune plasma with additional plasma-collection companies;*

- *our intention to enhance our current manufacturing capabilities;*

- *our intention to implement staff reductions when needed in order to adjust to lower plant utilization;*

- *our expectations regarding the potential market opportunities for our products and product candidates;*

- *our expectation that Kedrion Biopharma Inc. ("Kedrion") will purchase from us annual minimum quantities of KEDRAB during fiscal years 2024 through 2027, with aggregate revenues to us of approximately $180 million for such four-year period;*

- *our anticipation that KEDRAB's in market sales in the U.S. will continue to grow through the eight-year term of our new agreement with Kedrion;*

- *our belief that anti-rabies products based on equine serum are inferior to products made from human plasma;*

- *our belief that the exit of Sanofi S.A. from the U.S anti-Rabies IgG market, as well as some additional international markets, creates an opportunity for us to expand KEDRAB's U.S. market share;*

- *our belief that in light of the recent business combination of Kedrion and Bio Products Laboratories Ltd. ("BPL"), as well as the recent binding memorandum of understanding we entered into with Kedrion, we do not anticipate that BPL will continue to advance the development efforts for its anti-Rabies IgG product in the U.S. market;*

- *our belief that the administration of CYTOGAM together with the available antivirals may provide additional protection in preventing cytomegalovirus ("CMV") disease for certain high-risk transplant populations, such as lung and heart transplant;*

- *our belief that the administration of CYTOGAM together with the available antivirals may provide additional protection in preventing CMV disease for certain high-risk transplant populations, such as lung and heart transplant; and that there is an under-utilization of CYTOGAM as CMV prophylaxis in high-risk patients who undergo a solid organ transplant due to the lack of collection and presentation of new clinical and medical data and awareness regarding the benefits of combination of CYTOGAM and antiviral therapy, and that by addressing these deficits, increased utilization of CYTOGAM can be achieved;*

- *our intention to seek registration of CYTOGAM in various other territories as well as explore label expansion of CYTOGAM to be used in other indication;*

- *our belief that given the expected continued increase in liver transplants in ex-U.S. countries, and with our planned direct marketing efforts, HEPAGAM usage may grow;*

- *our expectation that sales of VARIZIG, WINRHO SDF and HEPGAM B will grow in 2024 in comparison to 2023;*

- *our expectation, based on Takeda's publication, that Takeda will commence sales of GLASSIA in Canada during 2024, following which we will be entitled to royalty income on such sales;*

- *our belief that our relationships with our strategic partners, including with Kedrion, Takeda and PARI, will continue without disruption;*

- *our belief that we will be able to register our proprietary products, including CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF, in additional countries where they are not currently registered, and our belief that this would lead to additional sales worldwide;*

- *our belief that we will be able to continue to meet our customers' demand for our proprietary products;*

- *our expectations regarding the potential actions or inactions of existing and potential competitors of our products, including our belief that there will be no new supplier of AAT by infusion in the U.S. market in the near future;*

- *our expectation that key U.S. physicians will publish new clinical data related to some of our products, and our belief that the educational symposiums that they conduct will have a positive impact on the understanding of our portfolio and thereby contributing to continued growth in demand;*

- *the legislation or regulation in countries where we sell our products that affect product pricing, reimbursement, market access or distribution channels may affect our sales and profitability;*

- *our projection that changes in the product sales mix and geographic sales mix may have an effect on our sales and profitability;*

- *our expectation to enter into discussions with the IMOH regarding the potential extension of the supply agreement for the snake bite antiserums prior to its expiration;*

- *our ability to identify growth opportunities for existing products and our ability to identify and develop new product candidates;*

- *our belief that the market opportunity for AAT products for the treatment of AATD will continue to grow;*

- *our expectation that the AATD's diagnosis will continue to increase going forward as awareness of AATD increases;*

- *our expectation that the number of patients treated for AATD will continue to increase going forward as awareness of AATD increases, and our expectation based on recent reimbursement approvals for treatment of AATD in a number of European countries that additional European countries will approve such reimbursement during the coming years;*

- *our plan to continue to develop our pipeline, primarily focusing on the pivotal Phase 3 InnovAATe clinical trial of Inhaled AAT for the treatment of Alpha-1 Deficiency (AATD) and to explore new strategic business development opportunities;*

- *our ability to attract partners for development programs for Inhaled AAT for AATD in the United States and the European Union, and to maintain such partnerships, if we decide to pursue such direction, as well as the impact on our business resulting from such partnerships, or from a failure to form such partnerships or fully realize the benefits of such partnerships;*

- *FDA's expressed willingness to potentially accept a P<0.1 alpha level in evaluating InnovAATe for meeting the efficacy primary endpoint for registration, which may allow for the acceleration of the program, and our plan to present a revised statistical analysis plan (SAP) and study protocol for the InnovAATe study and to seek the FDA's feedback by mid-2024;*

- *our belief that Inhaled AAT for AATD will increase patient convenience and reduce the need for patients to use intravenous infusions of AAT products, thereby decreasing the need for clinic visits or nurse home visits and reducing medical costs;*

- *our belief that Inhaled AAT for AATD will enable us to treat significantly more patients from the same amount of fraction IV and production capacity and therefore increase our profitability;*

- *our belief that the inhaled formulation of AAT would be more effective in reducing inflammation of the lung tissue and inhibiting the uncontrolled neutrophil elastase that causes the breakdown of the lung tissue and emphysema;*

- *our intention to conduct a sub-study in North America in which approximately 30 patients will be evaluated for the effect of ADA on AAT levels in plasma with Inhaled AAT and IV AAT treatments and our plan to initiate such study during 2025;*

- *our ability to obtain and/or maintain regulatory approvals for our products and new product candidates, the rate and degree of market acceptance, and the clinical utility of our products;*

- *our ability to maintain compliance with government regulations and licenses;*

- *our intention to vigorously defend ourselves against the lawsuit filed against us by a third-party distributor as a result of the termination of the distribution agreement for distribution of our proprietary products in Russia and Ukraine;*

- *our belief that our current cash and cash equivalents and expected future cash to be generated by our operational activities will be sufficient to satisfy our liquidity requirements for at least the next 12 months;*

- *our expectation that our capital expenditures will increase in the coming years mainly due to the planned expansion of our plasma collection operations as well as potentially to facilitate the transition of manufacturing of HEPGAM B, VARIZIG and WINRHO SDF to our manufacturing facility in Beit Kama, Israel;*

- *our expectations to pay approximately $15.0 million on account of contingent consideration, inventory related liability and the assumed liabilities under the asset purchase agreement entered into with Saol in November 2021, during the next 12 months;*

- *our ability to obtain and maintain protection for the intellectual property, trade secrets and know-how relating to or incorporated into our technology and products;*

- *our expectations regarding our ability to utilize Israeli tax incentives against future income; and*

- *our expectations regarding taxation, including that we will not be classified as a passive foreign investment company for the taxable year ending December 31, 2024.*

All forward-looking statements involve risks, assumptions and uncertainties. You should not rely upon forward-looking statements as predictors of future events. The occurrence of the events described, and the achievement of the expected results, depend on many events and factors, some or all of which may not be predictable or within our control. Actual results may differ materially from expected results. See the sections "Item 3. Key Information — D. Risk Factors" and "Item 5. Operating and Financial Review and Prospectus," as well as elsewhere in this Annual Report, for a more complete discussion of these risks, assumptions and uncertainties and for other risks, assumptions and uncertainties. These risks, assumptions and uncertainties are not necessarily all of the important factors that could cause actual results to differ materially from those expressed in any of our forward-looking statements. Other unknown or unpredictable factors also could harm our results.

All of the forward-looking statements we have included in this Annual Report are based on information available to us as of the date of this Annual Report and speak only as of the date hereof. We undertake no obligation, and specifically decline any obligation, to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this Annual Report might not occur.

The audited consolidated financial statements for the years ended December 31, 2023, 2022 and 2021 included in this Annual Report have been prepared in accordance with the international financial reporting standards ("IFRS") as issued by the international accounting standards board ("IASB").

Unless otherwise noted, NIS amounts presented in this Annual Report are translated at the rate of $1.00 = NIS 3.627, the exchange rate published by the Bank of Israel as of December 31, 2023.

We have proprietary rights to trademarks used in this Annual Report that are important to our business, many of which are registered under applicable intellectual property laws. Solely for convenience, trademarks and trade names referred to in this Annual Report may appear without the "®" or "™" symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent possible under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trademarks, trade names or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other companies. Each trademark, trade name or service mark of any other company appearing in this Annual Report is the property of its respective holder.

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

Our business, liquidity, financial condition, and results of operations could be adversely affected, and even materially so, if any of the risks described below occur. As a result, the trading price of our securities could decline, and investors could lose all or part of their investment. This Annual Report including the consolidated financial statements contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially and adversely from those anticipated, as a result of certain factors, including the risks facing the Company as described below and elsewhere in the Annual Report. You should carefully consider the risks and uncertainties included herewith. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. Material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, those relating to:

- *Our business is currently highly concentrated on our two leading products, KEDRAB and CYTOGAM, as well as on royalty income generated from GLASSIA sales by Takeda. Any adverse market event with respect to such products and income would have a material adverse effect on our business and financial condition.*

- *A significant portion of our net revenue has been and will continue to be driven from sales of our proprietary products, and in our largest geographic region, the United States. Any adverse market event with respect to some of our proprietary products or the United States would have a material adverse effect on our business.*

- *Our ability to maintain and expand sales of our commercial products portfolio in the U.S. and ex-U.S. markets is critical to our profitability and financial stability.*

- *We have excess manufacturing plant capacity in our manufacturing facility, which may result in reduction in operating profits, if not effectively managed.*

- *We have invested and intend to continue to invest in expanding our U.S. plasma collection operations in order to reduce our dependency on third-party suppliers in terms of plasma supply needs as well as to generate sales from commercialization of collected normal source plasma, and our ability to successfully expand this operation is important to support our future growth and profitability.*

- *We have several product development candidates, including our Inhaled AAT for AATD, as well as several other early-stage development projects. There can be no assurance that the development activities associated with these products will materialize and result in the FDA, EMA or any other relevant agencies granting us marketing authorization for any of these products.*

- *In our Proprietary Products segment, we rely on Kedrion for the sales of our KEDRAB product in the United States, and any disruption to our relationships with Kedrion would have an adverse effect on our future results of operations and profitability.*

- *Sales of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF in the U.S. market are critical in order to support future growth, future results of operations and profitability and any adverse market event with respect to such products would have an adverse effect on our future results of operations and profitability.*

- *We rely in large part on third parties for the sale, distribution and delivery of our products, and any disruption to our relationships with these third-party distributors would have an adverse effect on our future results of operations and profitability.*

- *Continued availability of several of our products in the Proprietary segment, is dependent on our ability to maintain existing engagements with contract manufacturing organizations to manufacture these products and any disruption to our relationship with such manufacturers would have an adverse effect on the availability of products, our future results of operations and profitability.*

- *Our Proprietary Product segment operates in a highly competitive market.*

- *We would become supply-constrained and our financial performance would suffer if we were unable to obtain adequate quantities of source plasma or plasma derivatives or specialty ancillary products that meet the regulatory requirement of the FDA, EMA, Health Canada or the regulatory authorities in Israel, or if our suppliers were to fail to modify their operations to meet regulatory requirements or if prices of the source plasma or plasma derivatives were to raise significantly.*

- *Our Distribution segment is dependent on a few suppliers, and any disruption to our relationship with these suppliers, or their inability to supply us with the products we sell, in a timely manner, in adequate quantities and/or at a reasonable cost, would have a material adverse effect on our business, financial condition and results of operations.*

- *Laws and regulations governing the conduct of international operations may negatively impact our development, manufacture, and sale of products outside of the United States and require us to develop and implement costly compliance programs.*

- *If our manufacturing facility in Beit Kama, Israel was to suffer a serious accident, contamination, force majeure event (including, but not limited to, a war, terrorist attack, earthquake, major fire or explosion etc.) materially affecting our ability to operate and produce saleable plasma-derived protein therapeutics, all of our manufacturing capacity could be shut down for an extended period.*

- *Our business and operations would suffer in the event of computer system failures, cyber-attacks on our systems or deficiency in our cyber security measures.*

- *Our success depends in part on our ability to obtain and maintain protection in the United States and other countries for the intellectual property relating to or incorporated into our technology and products, including the patents protecting our manufacturing process.*

- *We have incurred significant losses since our inception and while we were profitable in the year ended December 31, 2023 and the two years ended December 31, 2020, we incurred operating losses in the 2022 and 2021 fiscal years and may not be able to sustain profitability.*

- *Our business requires substantial capital, including potential investments in large capital projects, to operate and grow and to achieve our strategy of realizing increased operating leverage, for which we may incur debt or issue additional equity.*

- *Our share price may be volatile.*

- *Our business could be adversely affected by political, economic and military instability in Israel and its region.*

Risks Related to Our Business

Our business is currently highly concentrated on our two leading products, KEDRAB and CYTOGAM, as well as on royalty income generated from GLASSIA sales by Takeda. Any adverse market event with respect to such products and income would have a material adverse effect on our business and financial condition.

Our business currently relies on the sales of KEDRAB, our Human Rabies Immune Globulin (HRIG), and CYTOGAM, our Cytomegalovirus Immune Globulin Intravenous (Human) (CMV-IGIV), as well as royalty income on sales of GLASSIA, our intravenous AAT product, by Takeda. Revenue from sales of these products and royalties comprised approximately 23%, 12% and 11%, respectively (46% in total), of our total revenues for the year ended December 31, 2023.

In the event that KEDRAB or CYTOGAM were to lose significant sales or were to be substantially or completely displaced in the market, we would lose a significant and material source of our total revenues. Similarly, if these products were to become the subject of litigation and/or an adverse governmental action or ruling causing us to cease the manufacturing, export or sales of these products, our business and financial condition would be adversely affected.

We are entitled to royalty payments from Takeda on GLASSIA sales in the United States (as well as in Canada, Australia and New Zealand, to the extent GLASSIA will be approved and sales will be generated in these other markets) at a rate of 12% on net sales through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually, for each of the years from 2022 to 2040. For the year ended December 31, 2023 and the period between March and December 2022, we accounted for $16.1 million and $12.2 million, respectively, of sales-based royalty income from Takeda, and based on forecasted future growth, we project receiving royalties from Takeda in the range of $10 million to $20 million per year during 2024 to 2040. However, any reduction in sales of GLASSIA by Takeda or should Takeda reduce its manufacturing and marketing of GLASSIA for any reason (including but not limited to inability to adequately or sufficiently manufacture GLASSIA, regulatory limitations, difficulties in marketing, reduction in market size, or changes in corporate focus), our future expected royalty income from Takeda's sales of GLASSIA would be adversely impacted, which would have an adverse effect on our revenues and profitability.

A significant portion of our net revenue has been and will continue to be driven from sales of our proprietary products, and in our largest geographic region, the United States. Any adverse market event with respect to some of our proprietary products or the United States would have a material adverse effect on our business.

A significant portion of our revenues has been, and will continue to be, derived from sales of our proprietary products, including those of KEDRAB, CYTOGAM, HEPGAM B, VARIZIG, WINRHO SDF and GLASSIA, as well as royalty income from GLASSIA sales by Takeda. Revenue from our Proprietary products comprised approximately 81%, 79% and 73% of our total revenues for the years ended December 31, 2023, 2022 and 2021, respectively. If some of our proprietary products were to lose significant sales or were to be substantially or completely displaced in the market, we would lose a significant and material source of our total revenues. Similarly, if these products were to become the subject of litigation and/or an adverse governmental action or ruling causing us to cease the manufacturing, export or sales of these products, our business and financial condition would be adversely affected.

A significant portion of our sales and income are generated in the United States and comprised approximately 52%, 50% and 48% of our total revenues for the years ended December 31, 2023, 2022 and 2021, respectively. If our sales or income generated in the United States were significantly impacted by material changes to government or private payor reimbursement, other regulatory developments, competition or other factors, then our business and financial condition would be adversely affected.

Our ability to maintain and expand sales of our commercial products portfolio in the U.S. and ex-U.S. markets is critical to our profitability and financial stability.

Our Proprietary commercial products portfolio, comprising of KEDRAB, CYTOGAM, WINRHO SDF, VARIZIG, HEPGAM B and GLASSIA, as well as KAMRAB, KAMRHO (D) and two types of equine-based anti-snake venom (ASV) products, are currently distributed in the U.S. market, where we market and distribute some of these products directly based on our sales and marketing personnel, and in approximately 30 additional ex-U.S. international markets, including the Middle East and North Africa ("MENA") region, where we had little to no prior sales and operational experience prior to the consummation of the acquisition of CYTOGAM, WINRHO SDF, VARIZIG, HEPGAM B from Saol in November 2021. While we intend to leverage our existing strong international distribution network to grow our commercial revenue in the existing markets in which we sell our products, we also plan to expand to geographic markets in which these products are not currently sold, and we may not be successful in developing additional markets for these products.

Our ability to successfully maintain and expand our recently established U.S. based commercial and distribution infrastructure, and maintain and expand ex-U.S. commercialization, is critical for our future growth, profitability and financial stability. Given our limited prior experience in some of the required activities and responsibilities, including operation of direct sales in the U.S. market, knowledge and experience in the MENA region, as well as other operational, technical, regulatory, financial and compliance challenges, we may not be able to continue to expand our existing commercial operation, which may materially adversely affect the operating results of our business as well as our financial condition.

We have excess manufacturing plant capacity in our manufacturing facility, which may result in a reduction in operating profits, if not effectively managed.

Following the transition of GLASSIA manufacturing to Takeda in 2021, we have been and may continue to be affected by reduced efficiency of our manufacturing facility, which resulted and may continue to result in increased manufacturing costs per vial, reduced gross profitability and potential operating losses. We utilize the excess manufacturing capacity in our manufacturing plant to manufacture our proprietary products, including KEDRAB/KAMRAB, CYTOGAM and GLASSIA. We are also currently manufacturing at our plant small quantities of KAMRHO (D) and anti-snake venom products as well as clinical lots needed for the Inhaled AAT clinical study. In the future, we may potentially use the existing capacity for the manufacturing of HEPGAM B, VARIZIG and WINRHO SDF, which would be subject to a technology transfer and regulatory approvals and the execution of a new revised contract manufacturing agreement with Emergent. We may also consider utilizing our plant in the future for the manufacturing of products for other companies as a contract manufacturing organization (CMO). While we have the know-how and expertise to support the manufacturing of additional products in our facility, we may not be able to complete required technology transfers or obtain required regulatory approvals in the expected timeline, or at all. Further, while we are capable of increasing the manufacturing capacity at our facility, there is no assurance that there will be increased market demand for these products at a profitable market price in the markets in which we distribute our products or other markets. The manufacturing of excess quantities of products, which may not be sold due to lower demands, may result in the need to write-down the value of inventories, which may result in significant operating losses. See also "*—Manufacturing of new plasma-derived products in our manufacturing facility requires a lengthy and challenging development project and/or technology transfer project as well as regulatory approvals, all of which may not materialize*."

While we would expect to implement staff reductions when needed in order to adjust to lower plant utilization, the risk of not adequately adjusting to lower plant utilization could result in inefficiencies, reduced profitability or operating losses. Staff reductions have in the past, and may in the future, require us to pay excess severance compensation and may lead to labor disputes and strikes, which could affect our ability to continue to manufacture products and may lead to increased costs, reduced profitability and operating losses. For labor related risk see "*—We have entered into a collective bargaining agreement with the employees' committee and the Histadrut (General Federation of Labor in Israel), and we have incurred and could in the future incur labor costs or experience work stoppages or labor strikes as a result of any disputes in connection with such agreement.*"

Failure to adequately or timely adapt our manufacturing volume or the manufacturing volumes of our CMOs as needed, may lead to an inability to supply products, may have an adverse effect on our business and could cause substantial harm to our business reputation and result in breach of our sales agreements and the loss of future customers and orders.

We have invested, and intend to continue to invest, in expanding our U.S. plasma collection operations in order to reduce our dependency on third-party suppliers in terms of plasma supply needs as well as to generate sales from commercialization of collected normal source plasma, and our ability to successfully expand this operation is important to support our future growth and profitability.

In March 2021, we acquired the plasma collection center of B&PR in Beaumont, Texas, which primarily collects hyper-immune plasma used in the manufacture of our KAMRHO (D). In 2023, we significantly expanded our hyperimmune plasma collection in this center through obtaining FDA approval for the collection of hyper-immune plasma at this center to be used in the manufacture of KAMRAB and KEDRAB and commenced collections of such plasma during 2023. In March 2023, we entered into a lease agreement for a new plasma collection center in Uvalde, Texas and expect to commence operations at this new center during 2024, following the completion of its construction and obtaining the required regulatory approvals. The new center is planned to collect normal source plasma to be sold for manufacturing by third parties, as well as hyper-immune specialty plasma required for manufacturing of our proprietary products. We intend to leverage our experience with plasma collection to establish additional plasma collection centers in the United States, with the intention of collecting normal source plasma to be sold for manufacturing by third parties, as well as hyper-immune specialty plasma required for manufacturing of our proprietary products.

We believe that the expansion of our plasma collection operations will allow us to better support our plasma needs and reduce our dependency on third-party suppliers as well as generate revenues through sales from commercialization of collected normal source plasma. However, given our limited prior experience in managing plasma collection operations, the operational, technical, and regulatory challenges in establishing and maintaining plasma collection operations, as well as the challenges in screening locations, in negotiating the lease and other third party agreements required for the ongoing operations of the centers, the financial investment required to expand our collection capabilities and open new collection centers and the management of an expanded scope of plasma collection operations, we may not be able to realize our investment and the anticipated benefits of such activities. Further, we may not be able to adequately collect sufficient quantities of plasma through our plasma collection operations to support our plasma sourcing needs, which will result in continued dependency on third party suppliers; and even if we are successful in collection sufficient quantities, there can be no assurance that we will be able to reduce the cost of plasma through our collection operations, as compared to costs associated with procuring plasma from third parties. In addition, there could be no assurance that we will be able to collect adequate quantities of normal source plasma as well as secure supply agreements with customers at adequate prices. See also "*—We would become supply-constrained and our financial performance would suffer if we were unable to obtain adequate quantities of source plasma or plasma derivatives or specialty ancillary products approved by the FDA, the EMA, Health Canada or the regulatory authorities in Israel, or if our suppliers were to fail to modify their operations to meet regulatory requirements or if prices of the source plasma or plasma derivatives were to raise significantly"*; and *"—We may in the future engage in additional strategic transactions to acquire or sell assets, businesses, products or technologies or engage in in-license or out-license transactions of products or technologies or form collaborations that could negatively affect our operating results, dilute our stockholders' ownership or cause us to incur debt or significant expense."*

We have several product development candidates, including our Inhaled AAT for AATD as well as several other early-stage development projects. There can be no assurance that the development activities associated with these products will materialize and result in the FDA, EMA or any other relevant agencies granting us marketing authorization for any of these products.

We are engaged in research and development activities with respect to several pharmaceutical products candidates, including Inhaled AAT for AATD, which is our lead product development candidate.

During December 2019, the first patient was randomized in Europe into our pivotal Phase 3 InnovAATe clinical trial evaluating the safety and efficacy of our proprietary Inhaled AAT therapy for the treatment of AATD. The study was initiated following extensive discussions with both the FDA and EMA regarding the trial's design as well a thorough analysis of a prior pivotal Phase 2/3 clinical trial for Inhaled AAT for AATD conducted in Europe, which did not meet its primary or other pre-defined efficacy endpoints, and a prior Phase 2 clinical trial conducted in the U.S., which met its pharmacokinetic endpoint. In addition to the pivotal study and based on feedback received from the FDA regarding anti-drug antibodies ("ADA") to Inhaled AAT, we also intend to concurrently conduct a sub-study in North America in which approximately 30 patients will be evaluated for the effect of ADA on AAT levels in plasma with Inhaled AAT and IV AAT treatments. We recently received positive scientific advice from the EMA regarding the ongoing pivotal Phase 3 InnovAATe trial for Inhaled AAT that reconfirms the overall design of the study and acknowledges the statistically and clinically meaningful improvement in lung function (FEV1) demonstrated in our previously completed Phase 2/3 European study. Further, in January 2024, during a meeting with the FDA regarding the progress of the ongoing InnovAATe study, the FDA reconfirmed the overall design of the study and endorsed the Data and Safety Monitoring Board ("DSMB") unblinded positive safety assessment of 42 patients, accepting the DSMB's recommendation to waive the need for an additional safety assessment point of 60 patients with at least six months of treatment. During the meeting, the FDA also accepted our plan to conduct an open label extension study, which is expected to be initiated mid-2024, and expressed willingness to potentially accept a $P<0.1$ alpha level in evaluating InnovAATe for meeting the efficacy primary endpoint for registration, which may allow for the acceleration of the program. As a result, we plan to present a revised statistical analysis plan (SAP) and study protocol for the InnovAATe study and to seek the FDA's feedback by mid-2024. However, there can be no assurance that we will be able to complete the InnovAATe clinical trial successfully or that the trial results will be sufficient for obtaining FDA and EMA approval.

In addition, we are currently engaged in the early-stage development of other product candidates, including a recombinant AAT product candidate, and in 2023, we made progress in our three additional early-stage development programs, all of which are associated with plasma derived product candidates. There can be no assurance that the development activities associated with these products will materialize and result in the FDA, EMA or any other relevant agencies granting us marketing authorization for any of these products. For additional information, see — "Item 4. Information on the Company — *Our Development Product Pipeline.*" See also "*—Research and development efforts invested in our pipeline of specialty and other products may not achieve expected results"* and "*—If we are unable to successfully introduce new products and indications or fail to keep pace with advances in technology, our business, financial condition and results of operations may be adversely affected*."

We may in the future engage in additional strategic transactions to acquire or sell assets, businesses, products or technologies or engage in in-license or out-license transactions of products or technologies or form collaborations that could negatively affect our operating results, dilute our stockholders' ownership or cause us to incur debt or significant expense.

As part of our business development strategy, we have in the past, and may in the future engage in strategic transactions to acquire or sell assets, businesses, or products; or otherwise engage in in-licensing or out-licensing transactions with respect to products or technologies; or enter into other strategic alliances or collaborations. We may not identify additional suitable transactions, or complete such transactions in a timely manner, on a cost-effective basis, or at all. Moreover, we may devote resources to potential opportunities that are never completed, or we may incorrectly judge the value or worth of such opportunities. Even if we successfully execute a strategic transaction, we may not be able to realize the anticipated benefits of such transaction, may incur debt or assume unknown or contingent liabilities in connection therewith, and may experience losses related to our investments or dispositions. Integration of an acquired company or assets into our existing business or a transition of an asset to an acquirer or partner may not be successful and may disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, and require management resources that would otherwise focus on developing our existing business. Even if we are able to achieve the long-term benefits of a strategic transaction, our expenses and short-term costs may increase materially and adversely affect our liquidity. Any of the foregoing could have a material effect on our business, results of operations and financial condition.

Risks Related to Our Proprietary Products Segment

In our Proprietary Products segment, we rely on Kedrion for the sales of our KEDRAB product in the United States, and any disruption to our relationships with Kedrion would have an adverse effect on our future results of operations and profitability.

Pursuant to the strategic distribution and supply agreement with Kedrion for the marketing of KEDRAB in the United States, Kedrion is the sole distributor of KEDRAB in the United States. Sales to Kedrion accounted for approximately 23%, 13% and 12% of our total revenues in the years ended December 31, 2023, 2022 and 2021, respectively. We are dependent on Kedrion for its marketing and sales of KEDRAB in the United States. In December 2023, we entered into a binding memorandum of understanding with Kedrion for the amendment and extension of the distribution agreement between the parties, which represents the largest commercial agreement secured by us to date, according to which (among other things), the distribution agreement was extended until December 31, 2031, and Kedrion shall have the right to extend the agreement, by written notice no later than December 31, 2030, for an additional two years, until December 31, 2033. Under the terms of the binding memorandum of understanding, during fiscal years 2024 through 2027, Kedrion will purchase annual minimum quantities of KEDRAB, with aggregate revenues to us of approximately $180 million for such four-year period.

We currently also purchase from a subsidiary of Kedrion, KedPlasma LLC ("Kedplasma"), a large portion of the hyper-immune plasma which is used for the production of KEDRAB/KAMRAB. See "—*We would become supply-constrained, and our financial performance would suffer if we were unable to obtain adequate quantities of source plasma or plasma derivatives or specialty ancillary products approved by the FDA, the EMA, Health Canada or the regulatory authorities in Israel, or if our suppliers were to fail to modify their operations to meet regulatory requirements or if prices of the source plasma or plasma derivatives were to raise significantly*."

If we do not maintain the distribution relationship with Kedrion, we would be required to assume the sales and marketing activities of KEDRAB, or we would need to engage a replacement distributor for the product in the United States. Further, if we fail to maintain the plasma supply agreement with KedPlasma we would need to increase supply from other available sources and/or find a replacement supplier of the hyper-immune plasma which is used to manufacture KEDRAB/ KAMRAB. Establishing a relationship with a new distributor or supplier or internalizing those activities could lead to a decrease in KEDRAB/ KAMRAB sales and a deterioration in our market share when compared with one or more of our competitors. Any of the foregoing developments could have an adverse effect upon our sales, margins and profitability.

Sales of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF in the U.S. market are critical in order to support future growth, future results of operations and profitability.

Sales of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF in the U.S. market represented approximately 21% and 30% of our Proprietary Product segment sales for the years ended December 31, 2023 and 2022. Following the acquisition of these products in November 2021, we established a U.S. based commercial and sales team which gradually assumed the U.S. commercial responsibility for these products. Such activities included hiring employees with relevant U.S. commercial experience, engaging wholesalers, customers, and a U.S. third-party logistics ("3PL") provider, and understanding market landscape and trends for these products through market research and discussions with physicians and key opinion leaders, as well as medical affairs activities which include educating physicians, supporting medical publications and collecting new clinical data associated with these products.

However, given our limited prior experience in directly managing U.S. commercial and medical operations and the operational, technical and regulatory challenges in maintaining such activity, as well as the significant costs involved in such operations, we may not be able to realize the anticipated benefits of such activities, and may not be able to adequately maintain or expand market demand and continued product sales, which may result in significant reduction in sales, increased operating costs and reduced profitability.

See "*— Our ability to maintain and expand sales of our commercial products portfolio in the U.S. and ex-U.S. markets is critical to our profitability and financial stability."* See also – "Item 4. Information on the Company — *Proprietary Products Segment.*"

Continued availability of CYTOGAM is dependent on our ability to maintain continuous plasma supply and maintain our relationship with third-party contract manufacturers and suppliers.

As part of the acquisition of the four FDA approved plasma-derived hyperimmune commercial products from Saol, we acquired inventory of CYTOGAM which was sufficient to meet market demand through the second part of 2023. During December 2022, we submitted a prior approval supplement ("PAS") to the FDA for approval to manufacture CYTOGAM. In May 2023, we received FDA approval to manufacture CYTOGAM at our facility in Beit Kama, Israel, and CYTOGAM manufactured at our Israeli facility is now available for commercial sale in the United States. A similar application to the Canadian health authorities was submitted in January 2023 and was approved in July 2023.

As part of the initiation of the CYTOGAM technology transfer process, we engaged Prothya Biosolutions Belgium ("Prothya") as a third-party contract manufacturer to perform certain manufacturing activities required for the manufacturing of CYTOGAM. In addition, CMV hyper-immune plasma for the manufacturing of CYTOGAM is supplied by CSL Behring Ltd. ("CSL Behring"), initially under a three-year supply agreement that we assumed from Saol, and in December 2023, we entered into a plasma supply agreement directly with CSL Behring that supersedes the assumed supply agreement and provides for the continued supply of required plasma for the manufacturing of the product for each of the years 2024-2026. If we fail to maintain our relationship with these entities, we could face supply shortages, which could adversely impact our ability to manufacture and supply CYTOGAM, and could incur increased costs in finding replacement vendors. Delays in establishing a relationship with new vendors could lead to a decrease in CYTOGAM sales and a deterioration in our market position when compared with one or more of our competitors. Any of the foregoing developments could have an adverse effect upon our sales, margins and profitability.

In our Proprietary Products segment, we currently earn royalties on GLASSIA sales by Takeda in the United States (and in the future may earn royalties on GLASSIA sales by Takeda in Canada, Australia and New Zealand, to the extent GLASSIA will be approved for sale and sales will be generated in these other markets), and any reduction in sales of GLASSIA by Takeda would have an adverse effect on our future expected royalty income and profitability.

Commencing in March 2022, we have been entitled to royalty payments from Takeda on GLASSIA sales in the United States (and in the future we may earn royalties on GLASSIA sales by Takeda in Canada, Australia and New Zealand, to the extent GLASSIA will be approved and sales will be generated in these other markets) at a rate of 12% on net sales through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually, for each of the years from 2022 to 2040. For the year ended December 31, 2023, and the period between March and December 2022, we accounted for $16.1 million and $12.2 million, respectively, of sales-based royalty income from Takeda, and based on forecasted future growth, we project receiving royalties from Takeda in the range of $10 million to $20 million per year for 2024 to 2040. However, any reduction in sales of GLASSIA by Takeda or should Takeda reduce its manufacturing and marketing of GLASSIA for any reason (including but not limited to inability to adequately or sufficiently manufacture GLASSIA, regulatory limitations, difficulties in marketing, reduction in market size, or changes in corporate focus), our future expected royalty income from Takeda's sales of GLASSIA would be adversely impacted, which would have an adverse effect on our results of operations and profitability.

Continued availability of several of our products in the Proprietary Products segment is dependent on our ability to maintain existing engagements with contract manufacturing organizations to manufacture these products and any disruption to our relationship with such manufacturers would have an adverse effect on the availability of products, our future results of operations and profitability.

HEPAGAM B, VARIZIG and WINRHO SDF are currently manufactured by Emergent under a contract manufacturing agreement which was assigned to us from Saol following the consummation of the acquisition. We are dependent on Emergent to secure the supply of adequate quantities of plasma needed to timely manufacture these products and we rely on their manufacturing, quality and regulatory systems to ensure that the manufacturing process complies with current Good Manufacturing Practice ("cGMP") standards and any other regulatory requirements and that each product manufactured meets its specifications and is appropriately released for human consumption.

If we fail to maintain our relationship with Emergent, or if Emergent fails to operate in compliance with cGMP and other regulatory requirements, we could face supply shortages and may not be able to supply these products. In addition, such failure may result in increased costs and delays in transferring the manufacturing of the products to our plant in Beit Kama, Israel, or in finding a replacement manufacturer for these products and we might be required to identify replacement supplier of the plasma which is used for the production of these products. Delays in internalizing the production or establishing a relationship with a new manufacturer could lead to a decrease in these products' sales and a deterioration in our market share when compared with one or more of our competitors. Any of the foregoing developments could have an adverse effect upon our sales, margins and profitability.

We have also engaged Prothya as a third-party contract manufacturer to perform certain manufacturing activities required for the manufacturing of CYTOGAM. If we fail to maintain our relationship with Prothya, or if Prothya fails to operate in compliance with cGMP and other regulatory requirements, we could face supply shortages, which could adversely impact our ability to manufacture and supply CYTOGAM and could incur increased costs in finding a replacement manufacturer for this product. Delays in establishing a relationship with a new manufacturer could lead to a decrease in this product sales and a deterioration in our market share when compared with one or more of our competitors. Any of the foregoing developments could have an adverse effect upon our sales, margins and profitability.

Certain of our sales in our Proprietary Products segment rely on our ability to win tender bids based on the price and availability of our products in public tender processes.

Certain of our sales in our Proprietary Products segment rely on our ability to win tender bids in certain markets, including those of the World Health Organization (WHO) and other similar health organizations. Our ability to win bids may be materially adversely affected by competitive conditions in such bid process. Our existing and new competitors may also have significantly greater financial resources than us, which they could use to promote their products and business. Greater financial resources would also enable our competitors to substantially reduce the price of their products or services. If our competitors are able to offer prices lower than us, our ability to win tender bids during the tender process will be materially affected and could reduce our total revenues or decrease our profit margins.

We rely in large part on third parties for the sale, distribution and delivery of our products, and any disruption to our relationships with these third-party distributors would have an adverse effect on our future results of operations and profitability.

We engage third party distributors to distribute and sell our Proprietary Products in ex-U.S. markets (other than the Israeli market), including CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF. Sales through such distributors accounted for approximately 26%, 25% and 17% of our total revenues in the years ended December 31, 2023, 2022 and 2021, respectively, and we expect such sales to increase in 2024 and beyond. We are dependent on these third parties for successful marketing, distribution and sales of our products in these markets. If such third parties were to breach, terminate or otherwise fail to perform under our agreements with them, our ability to effectively distribute our products would be impaired and our business could be adversely affected. Moreover, circumstances outside of our control, such as a general economic decline, market saturation or increased competition, may influence the successful renegotiation of our contracts or the securing of favorable terms.

In addition to distribution and sales, these third-party distributors are, in some cases, responsible for the regulatory registration of our products in the local markets in which they operate, as well as responsible for participation in tenders for sale of our products. Failure of these third-party distributors to obtain and maintain such regulatory approvals and/or win tenders or provide competitive prices to our products may adversely affect our ability to sell our Proprietary Products in these markets, which in turn will negatively affect our revenues and profitability. In addition, our inability to sell our Proprietary Products in these markets may reduce our manufacturing plant utilization and effectiveness and may lead to additional reduction of profitability.

In the U.S. market we utilize a 3PL provider in connection with the distribution of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF, which provides complete order to cash services. If such 3PL provider were to breach, terminate or otherwise fail to adequately perform under our agreement with it, including inadequate inventory management, transportation delays and incorrect temperature control during storage and handling, fails to issue invoices correctly or on a timely basis and/or fails to collect payments due to us from our U.S. customers, our ability to effectively distribute such products would be impaired, which could negatively impact our business operations and financial performance.

Disputes with distributors have arisen in the past and disputes may arise in the future, that cause the delay or termination of the development, manufacturing, supply or commercialization of our product candidates, or could result in costly litigation or arbitration that diverts management's attention and resources. In May 2022, we terminated a distribution agreement with a third-party engaged to distribute our propriety products in Russia and Ukraine (the "Distributor") and a power of attorney granted in connection with such distribution agreement to an affiliate of the Distributor (the "Affiliate"). In July 2022, the Affiliate filed a request for a conciliation hearing with the court in Geneva relying on the terminated power of attorney and seeking damages for the alleged inability to sell the remaining product inventory previously acquired from the Company and compensation for the lost customer base. The conciliation hearing was held on March 17, 2023, and the Affiliate was granted authorization to proceed to file a Statement of Claim before the competent tribunal within three months. On June 13, 2023, the Affiliate filed its Statement of Claim with the tribunal of first instance in Geneva, seeking alleged damages in the total amount of $6.7 million. We were officially notified of such filing on November 17, 2023. We have filed a motion with the tribunal of first instance in Geneva challenging its jurisdiction over the Affiliate's claims, submitting that such claims should have been brought before an arbitral tribunal, as contractually agreed between the parties. Until the tribunal of first instance in Geneva rules on the motion, the Affiliate's claims will not be heard. At this time, it is not possible to assess the prospects of the claim against us and any potential liabilities and impact on our business. See "Item 4. Information on the Company — Legal Proceedings."

Our Proprietary Products segment operates in a highly competitive market.

Our Proprietary Products compete with products distributed by well-established biopharmaceutical companies, including several large competitors in the plasma industry. These large competitors include CSL Behring, Takeda, and Grifols S.A. ("Grifols"), which acquired a previous competitor, Talecris Biotherapeutics, Inc. ("Talecris") in 2011, Octapharma, Kedrion (other than for KEDRAB), Biotest AG and ADMA Biologics Inc. ("ADMA"). We compete against these companies for, among other things, licenses, expertise, clinical trial patients and investigators, consultants and third-party strategic partners. We also compete with these companies for market share for certain products in the Proprietary Products segment. Our large competitors have advantages in the market because of their size, financial resources, markets and the duration of their activities and experience in the relevant market, especially in the United States and countries of the European Union. As a result, they may be able to devote more funds to research and development and new production technologies, as well as to the promotion of their products and business. These competitors may also be able to sustain longer periods of substantial reduction in the price of their products or services. These competitors also have an additional advantage regarding the availability of raw materials, as they own or control multiple plasma collection centers and/or plasma fractionation facilities.

In addition, our plasma-derived protein therapeutics face, or may face in the future, competition from existing or newly developed non-plasma products and other courses of treatments. New treatments, such as antivirals, gene therapies, small molecules, correctors, monoclonal or recombinant products, may also be developed for indications for which our products are now used, as well as courses of treatments such as subcutaneous treatment.

Our products generally do not benefit from patent protection and compete against similar products produced by other providers. Additionally, the development by a competitor of a similar or superior product or increased pricing competition may result in a reduction in our net sales or a decrease in our profit margins.

Our hyper-immune IgG products in the Proprietary Products segment face competition from several competing plasma derived products and non-plasma derived pharmaceuticals, mainly anti-viral.

KEDRAB/KAMRAB. We believe that there are two main competitors for KEDRAB/KAMRAB, our anti-rabies products worldwide: Grifols, whose product we estimate comprises the majority of the anti-rabies IgG market in the United States, and CSL Behring, which sells its anti-rabies product in Europe and elsewhere. Sanofi Pasteur, the vaccines division of Sanofi S.A., exited the U.S anti-rabies IgG market as well as some additional international markets, however, may still be competing in other markets or in the future could return to exited markets. BPL, which has an anti-Rabies IgG product for the UK market, has developed it also for the U.S. market, including performing a clinical trial; however, in light of the recent business combination of Kedrion and BPL, as well as the recent binding memorandum of understanding we entered into with Kedrion, we do not anticipate that BPL will continue to advance the development efforts for its anti-Rabies IgG product in the U.S. market. There are several local producers in other countries that make anti-rabies IgG products, mostly based on equine serum. Over the past several years, several companies have made attempts, and some are still in the process of developing monoclonal antibodies for an anti-rabies treatment. These products, if approved, may be as effective as the currently available plasma derived anti-rabies IgG and may potentially be significantly cheaper, and as such may result in loss of market share of KEDRAB/KAMRAB.

CYTOGAM. To our knowledge, CYTOGAM is the sole plasma derived CMV IgG product approved for sale in the United States and Canada. Based on available public information, the FDA approved the following antiviral drugs for the prevention of CMV infection and disease: Letermovir (Prevymis), developed by Merck & Co., and for treatment of refractory/resistant infection, Maribavir (Livtencity), developed by Takeda, which may result in the loss of market share for CYTOGAM. Currently, treatment guidelines state that combination therapy with standard antiviral can be considered for certain solid organ transplant recipients. The most commonly used antivirals are Ganciclovir (Cytovene-IV Roche) and Valganciclovir (Valcyte Roche). Patients treated with antiviral agents for a long time can develop resistance and will require a second-line treatment such as Foscarnet (Foscavir Pfizer) or Cidofovir (Gilead Sciences). In rest of the world ("ROW") markets, Cytotec CP (Biotest), a plasma derived competing product is available. Despite the introduction of newer antiviral therapies for CMV in solid organ transplantation, there is a growing need to determine the optimal approach of CMV management when considering all available therapies, including CYOTGAM.

WINRHO SDF. In the United States, WINRHO SDF competes with corticosteroids (oral prednisone or high-dose dexamethasone) or intravenous immune globulin ("IVIG") (Grifols, CSL Behring and Takeda are the main manufacturers and suppliers in the U.S.) as first line treatment of acute ITP, with IVIG or WINRHO SDF recommended for pediatric patients in whom corticosteroids are contraindicated. IVIG has similar efficacy to WINRHO SDF, and ITP is its labeled indication for IVIG. Rhophylac (CSL Behring) is also approved for ITP treatment, but we believe it is mostly used for Hemolytic Disease of the Newborn ("HDN"), due to its comparatively small vial size. For HDN indication, the market is usually led by tenders, where key indicators are registration status and price, and the main multiple competitors in Canada and ROW countries are RhoGAM (Kedrion), Hyper RHO (Grifols), Rhophylac (CSL Behring) and our KAMRHO (D).

HEPAGAM B. To our knowledge, in the United States, HEPAGAM B is the only approved HBIG with an on-label indication for Liver Transplants. To our understanding, HEPAGAM B holds the majority market share for the indication, while another HBIG (Nabi-HB manufactured and supplied by ADMA) is being used off-label by some medical centers for the indication. In recent years, duration of treatment has been reduced by physicians. New generation antivirals are considered effective for preventing HBV reactivation post-transplant, hence limiting HBIG use. Post-exposure prophylaxis ("PEP") indication in the United States is covered almost totally by Nabi-HB (ADMA) and HyperHEP (Grifols). In Canada, main competition in national tenders is HyperHEP. In ROW countries such as Turkey, Saudi-Arabia and Israel, HEPATECT and Zutectra (Biotest AG) represent the primary competition.

VARIZIG. In the United States, incidence of Varicella Zoster Virus ("VZV") infection has decreased dramatically since the introduction of the varicella vaccine in 1995. Two vaccines containing varicella virus are licensed for use in the United States. Varivax is the single-antigen varicella vaccine. ProQuad is a combination measles, mumps, rubella, and varicella (MMRV) vaccine. Although the use of the vaccine has reduced the frequency of chickenpox, the virus, has not been eradicated. Moreover, incidence of Herpes Zoster, also caused by VZV, is increasing among adults in the United States. Suboptimal vaccination rates contribute to outbreaks and increased risk of VZV exposure. Immunocompromised population and other patient groups are at high risk for severe varicella and complications, after being exposed to VZV. In the U.S. market VARIZIG is the single FDA-approved product and recommended by the Centers for Disease Control ("CDC") for post-exposure prophylaxis of varicella for persons at high risk for severe disease who lack evidence of immunity to varicella. Alternative, CDC recommendations include IVIG if VARIZIG is unavailable and some experts recommend using Acyclovir, Valacyclovir, although published data on the benefits of acyclovir as post-exposure prophylaxis among immunocompromised people is limited. In ROW markets, several plasma derived competitor products are available, such as VARITECT (Biotest) and others.

KAMRHO (D). We market KAMRHO (D) for HDN mainly in Israel, Argentina and Chile. Kedrion is one of our competitors for KAMRHO (D) in some of those international markets. We believe there are currently two additional main suppliers of competitive products, Grifols and CSL Behring. There are also local producers in other countries that make similar products mostly intended for local markets.

Our market share of the AAT product could be negatively impacted by new competitors or adoption of new methods of administration.

We believe that our two main competitors in the AAT market are Grifols and CSL Behring. We estimate that Grifols' AAT by infusion product for the treatment of AATD, Prolastin A1PI, accounts for at least 50% market share in the United States and more than 70% of sales in the worldwide market for the treatment of AATD, which also includes sales of Prolastin in different European countries. To the best of our knowledge, since 2018, Grifols sell Prolastin Liquid, a ready-to-infuse solution of AAT, in the United States. Apart from its sales through Talecris' historical business, Grifols is also a local producer of the product in the Spanish market and operates in Brazil. CSL Behring's intravenous AAT product, Zemaira, is mainly sold in the United States. In 2015, CSL Behring's intravenous AAT product, Respreeza, was granted centralized marketing authorization in Europe and CSL Behring has launched the product in a few European countries since 2016. There is another, smaller local producer in the French market, LFB S.A. In addition, we estimate that each of Grifols and CSL Behring owns more than 300 operating plasma collection centers located across the United States.

Several of our competitors are conducting preclinical and clinical trials for the development of gene therapy, recombinant AAT, small molecule treatment or correctors for AATD. For example, in January 2024, Inhibrx and Sanofi announced that the companies have entered into a definitive agreement under which Aventis Inc., a subsidiary of Sanofi, will acquire all the assets and liabilities associated with INBRX-101, which was indicated to be in a registrational trial for the treatment of patients with alpha-1 antitrypsin deficiency. While these products are not yet in pivotal trial or in late stages of development, they may eventually be successfully developed and launched, and could adversely impact our revenue and growth of sales of GLASSIA or GLASSIA-related royalties as well as affect our ability to launch our Inhaled AAT product, if approved.

Similarly, if a new AAT formulation or a new route of administration with significantly improved characteristics is adopted (including, for example, aerosol inhalation or self-administering by way of subcutaneous route of administration), the market share of our current AAT product, GLASSIA, could be negatively impacted. While we are in the process of developing Inhaled AAT for AATD, our competitors may also be attempting to develop similar products. For example, several of our competitors may have completed early-stage clinical trials for the development of an inhaled formulation of AAT for different indications. While these products are in the early stages of development, they may eventually be successfully developed and launched. Furthermore, even if we are able to commercialize Inhaled AAT for AATD prior to the development of comparable products by our competitors, sales of Inhaled AAT for AATD, subject to approval of such product by the applicable regulatory authorities, could adversely impact our revenue and growth of sales of GLASSIA or GLASSIA -related royalties.

Our products involve biological intermediates that are susceptible to contamination and the handling of such intermediates and our final products throughout the supply chain and manufacturing process requires cold-chain handling, all of which could adversely affect our operating results.

Plasma and its derivatives are raw materials that are susceptible to damage and contamination and may contain microorganisms that cause diseases in humans, commonly known as human pathogens, any of which would render such materials unsuitable as raw material for further manufacturing. Almost immediately after collection from a donor, plasma and plasma derivatives must be stored and transported at temperatures that are at least -20 degrees Celsius (-4 degrees Fahrenheit). Improper storage or transportation of plasma or plasma derivatives by us or third-party suppliers may require us to destroy some of our raw material. In addition, plasma and plasma derivatives are also suitable for use only for certain periods of time once removed from storage. If unsuitable plasma or plasma derivatives are not identified and discarded prior to release to our manufacturing processes, it may be necessary to discard intermediate or finished products made from such plasma or plasma derivatives, or to recall any finished product released to the market, resulting in a charge to cost of goods sold and harm to our brand and reputation. Furthermore, if we distribute plasma-derived protein therapeutics that are produced from unsuitable plasma because we have not detected contaminants or impurities, we could be subject to product liability claims and our reputation would be adversely affected.

Despite overlapping safeguards, including the screening of donors and other steps to remove or inactivate viruses and other infectious disease-causing agents, the risk of transmissible disease through plasma-derived protein therapeutics cannot be entirely eliminated. If a new infectious disease was to emerge in the human population, the regulatory and public health authorities could impose precautions to limit the transmission of the disease that would impair our ability to manufacture our products. Such precautionary measures could be taken before there is conclusive medical or scientific evidence that a disease poses a risk for plasma-derived protein therapeutics. In recent years, new testing and viral inactivation methods have been developed that more effectively detect and inactivate infectious viruses in collected plasma. There can be no assurance, however, that such new testing and inactivation methods will adequately screen for, and inactivate, infectious agents in the plasma or plasma derivatives used in the production of our plasma-derived protein therapeutics. Additionally, this could trigger the need for changes in our existing inactivation and production methods, including the administration of new detection tests, which could result in delays in production until the new methods are in place, as well as increased costs that may not be readily passed on to our customers.

Plasma and plasma derivatives can also become contaminated through the manufacturing process itself, such as through our failure to identify and purify contaminants through our manufacturing process or failure to maintain a high level of sterility within our manufacturing facilities.

Once we have manufactured our plasma-derived therapeutics, they must be handled carefully and kept at appropriate temperatures. Our failure, or the failure of third parties that supply, ship, store or distribute our products, to properly care for our plasma-derived products, may result in the requirement that such products be destroyed.

While we expect work-in-process inventories scraps in the ordinary course of business because of the complex nature of plasma and plasma derivatives, our processes and our plasma-derived therapeutics, unanticipated events may lead to write-offs and other costs in amounts materially higher than our expectations. We have, in the past, experienced situations that have caused us to write-off the value of inventories. Such write-offs and other costs could materially adversely affect our operating results. Furthermore, contamination of our plasma-derived protein therapeutics could cause consumers or other third parties with whom we conduct business, to lose confidence in the reliability of our manufacturing procedures, which could materially adversely affect our sales and operating results.

Our ability to continue manufacturing and distributing our plasma-derived therapeutics depends on continued adherence by us and contract manufacturers to current Good Manufacturing Practice regulations.

The manufacturing processes for our products are governed by detailed written procedures and regulations that are set forth in cGMP requirements for blood products, including plasma and plasma derivative products. Failure to adhere to established procedures or regulations, or to meet a specification set forth in cGMP requirements, could require that a product or material be rejected and destroyed. There are relatively few opportunities for us or contract manufacturers to rework, reprocess or salvage nonconforming materials or products. Any failure in cGMP inspection will affect marketing in other territories, including the U.S. and Israel.

The adherence by us and our contract manufacturers to cGMP regulations and the effectiveness of applicable quality control systems are periodically assessed through inspections of the manufacturing facility, including our manufacturing facility in Beit Kama, Israel, by the FDA, the IMOH and regulatory authorities of other countries. Such inspections could result in deficiency citations, which would require us or our contract manufacturers to take action to correct those deficiencies to the satisfaction of the applicable regulatory authorities. If serious deficiencies are noted or if we or our contract manufacturers are unable to prevent recurrences, we may have to recall products or suspend operations until appropriate measures can be implemented. The FDA could also stop the import of products into the United States if there are potential deficiencies. Such deficiencies may also affect our ability to obtain government contracts in the future. We are required to report certain deviations from procedures to the FDA. Even if we determine that the deviations were not material, the FDA could require us or our contract manufacturers to take certain measures to address the deviations. Since cGMP reflects ever-evolving standards, we regularly need to update our manufacturing processes and procedures to comply with cGMP. These changes may cause us to incur additional costs and may adversely impact our profitability. For example, more sensitive testing assays (if and when they become available) may be required or existing procedures or processes may require revalidation, all of which may be costly and time-consuming and could delay or prevent the manufacturing of a product or launch of a new product.

We may face manufacturing stoppages and other challenges associated with audits or inspections by regulatory agencies.

The regulatory authorities may, at any time and from time to time, audit the facilities in which our products are manufactured. If any such inspection or audit of such facilities identifies a failure to comply with applicable regulations, or if a violation of our product specifications or applicable regulations occurs independently of such an inspection or audit, the relevant regulatory authority may require remedial measures that may be costly or time consuming for us to implement and that may include the temporary or permanent suspension of commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or with whom we contract, could materially harm our business.

Manufacturing of new plasma-derived products in our manufacturing facility requires a lengthy and challenging development project and/or technology transfer project as well as regulatory approvals, all of which may not materialize.

The manufacturing of newly marketed or investigational plasma-derived products in our plant, including our Proprietary Products currently manufactured by third parties, requires a lengthy and challenging development project and/or technology transfer project through which we transfer the know-how and capabilities to manufacture the new product. Such projects are usually complex and involve investment of significant time (approximately three to four years) and resources. There is no assurance that such development and/or technology transfer projects will be successful and will allow us to manufacture the new product according to its required specifications.

Such development and/or technology transfer projects require regulatory approval by the FDA and/or EMA and/or Health Canada or other relevant regulatory agencies. Obtaining such regulatory approval may require activities such as the manufacturing of comparable batches and/or performing comparability non-clinical and/or clinical studies between the product manufactured by its existing manufacturer and the product manufactured at our manufacturing facility. There is no assurance that we will be able to provide supporting comparability results that meet all regulatory requirements needed to obtain the regulatory approval required to be able to commence commercial manufacturing of new plasma-derived products in our manufacturing plant.

If we are unable to adequately complete the required development and/or technology transfer projects or subsequently obtain the required regulatory approvals, we will not be able to meet commercial demand, utilize the excess capacity of our manufacturing plant, incur additional costs and may suffer reduced profitability or operating losses.

We would become supply-constrained and our financial performance would suffer if we were unable to obtain adequate quantities of source plasma or plasma derivatives or specialty ancillary products that meet the regulatory requirement of the FDA, EMA, Health Canada or the regulatory authorities in Israel, or if our suppliers were to fail to modify their operations to meet regulatory requirements or if prices of the source plasma or plasma derivatives were to raise significantly.

Our proprietary products depend on our access to U.S., European or other territories' hyper-immune plasma or plasma derivatives, such as fraction IV. We purchase these plasma products from third-party licensed suppliers, some of which are also responsible for the plasma fractionation process, pursuant to multiple purchase agreements. We have entered into (and in connection with our acquired four FDA approved products, we assumed) a number of plasma supply agreements with various third parties in the United States and Europe. These agreements contain various termination provisions, including upon a material breach of either party, force majeure and, with respect to supply agreements with strategic partners, the failure or delay on the part of either party to obtain the applicable regulatory approvals or the termination of the principal strategic relationship. If we are unable to obtain adequate quantities of source plasma or fraction IV plasma that meet the regulatory requirements of the FDA, the EMA or the regulatory authorities in Israel from these providers, we may be unable to find an alternative cost-effective source.

In order for plasma and fraction IV plasma to be used in the manufacturing of our plasma-derived protein therapeutics, the individual centers at which the plasma is collected must be registered with and meet the regulatory requirements of the relevant regulatory authorities, such as the FDA and EMA. When a new plasma collection center is opened, and on an ongoing basis after its registration, it must be inspected by the FDA, the EMA or the regulatory authorities in Israel for compliance with cGMP and other regulatory requirements. An unsatisfactory inspection could prevent a new center from being established or lead to the suspension or revocation of an existing registration. If relevant regulatory authorities determine that a plasma collection center did not comply with cGMP in collecting plasma, we may be unable to use and may ultimately destroy plasma collected from that center, which may impact on our ability to timely meet our manufacturing and supply obligations. Additionally, if noncompliance in the plasma collection process is identified after the impacted plasma has been pooled with compliant plasma from other sources, entire plasma pools, in-process intermediate materials and final products could be impacted, such as through product destruction or rework. Consequently, we could experience significant inventory impairment provisions and write-offs, which could adversely affect our business and financial results.

In addition, the plasma supplier's fractionation process must also meet standards of the FDA, the EMA or the regulatory authorities in Israel. If a plasma supplier is unable to meet such standards, we will not be able to use the plasma derivatives provided by such supplier, which may impact on our ability to timely meet our manufacturing and supply obligations.

If we were unable to obtain adequate quantities of source plasma or plasma derivatives that meet the regulatory standards of the FDA, the EMA, Health Canada or the regulatory authorities in Israel, we would be limited in our ability to maintain or increase current manufacturing levels of our plasma derivative products, as well as in our ability to conduct the research required to maintain our product pipeline. As a result, we could experience a substantial decrease in total revenues or profit margins, a potential breach of distribution agreements, a loss of customers, a negative effect on our reputation as a reliable supplier of plasma derivative products or a substantial delay in our production and strategic growth plans.

The ability to increase plasma collections may be limited, our supply of plasma and plasma derivatives could be disrupted or the cost of plasma and plasma derivatives could increase substantially, as a result of numerous factors, including a reduction in the donor pool, increased regulatory requirements, decreased number of plasma supply sources due to consolidation and new indications for plasma-derived protein therapeutics, which could increase demand for plasma and plasma derivatives and lead to shortages.

The plasma collection process is dependent on donors arriving in plasma collection centers and agreeing to donate plasma. Factors such as changes in reimbursement rates, competition for donors, and declining donor loyalty may lead to a decrease in the number of donors, which may negatively impact our ability to obtain adequate quantities of plasma. During major healthcare events (such as during the COVID-19 pandemic) the number of donors attending plasma collection centers decreases, which may adversely affect the availability of plasma and its derivatives. A significant shortage in plasma supply may adversely affect our ability to continue manufacturing our products, may result in shortages in our products in the market, and may result in reduced sales and profitability.

We are also dependent on a number of suppliers who supply specialty ancillary products used in the production process, such as specific gels and filters. Each of these specialty ancillary products is provided by a single, exclusive supplier. If these suppliers were unable to provide us with these specialty ancillary products, if our relationships with these suppliers deteriorate, if these suppliers fail to meet our vendors qualification processes, or if these suppliers' operations are negatively affected by regulatory enforcement due to noncompliance, the manufacture and distribution of our products would be materially adversely affected, which would adversely affect our sales and results of operations. See "*—If we experience equipment difficulties or if the suppliers of our equipment or disposable goods fail to deliver key product components or supplies in a timely manner, our manufacturing ability would be impaired and our product sales could suffer."*

Some of our required specialty ancillary products and other materials used in the manufacturing process are commonly used in the healthcare industry world-wide. If the global demand for these products increases due to healthcare issues, epidemics or pandemics, our ability to secure adequate supply at reasonable cost of such products may be negatively affected, which would materially adversely affect our ability to manufacture and distribute our products, which would adversely affect our sales and results of operations.

In addition, regulatory requirements, including cGMP regulations, continually evolve. Failure of our plasma suppliers to adjust their operations to conform to new standards as established and interpreted by applicable regulatory authorities would create a compliance risk that could impair our ability to sustain normal operations.

In addition, if the purchase prices of the source plasma or plasma derivatives that we use to manufacture our proprietary products were to rise significantly, we may not be able to pass along these increased plasma and plasma-derivative prices to our customers. Prices in many of our principal markets are subject to local regulation and certain pharmaceutical products, such as plasma-derived protein therapeutics, are subject to price controls. Any inability to pass costs on to our customers due to these factors or others would reduce our profit margins. In addition, most of our competitors have the ability to collect their own source plasma or produce their own plasma derivatives, and therefore their products' prices would not be impacted by such a price rise, and as a result any pricing changes by us in order to pass higher costs on to our customers could render our products noncompetitive in certain territories.

Disruption of the operations of our current or any future plasma collection center due to regulatory impediments or otherwise would cause us to become supply constrained and our financial performance would suffer.

In March 2021, we completed the acquisition of the FDA licensed plasma collection center and certain related assets from the privately held B&PR based in Beaumont, Texas, which initially specialized in the collection of hyper-immune plasma used in the manufacture KAMRHO (D). In 2023, we significantly expanded our hyperimmune plasma collection in this center by obtaining FDA approval for the collection of hyper-immune plasma at this center to be used in the manufacture of KAMRAB and KEDRAB, and commenced collections of such plasma during 2023. In March 2023, we entered into a lease for a new plasma collection center in Uvalde, Texas and expect to commence operations at this new center in 2024, following the completion of its construction and obtaining the required regulatory approvals. During early 2024, we plan to lease a subsequent facility and initiate construction activities to establish our third plasma collection center. We intend to further leverage our experience with plasma collection to establish additional plasma collection centers in the United States, with the intention of collecting normal source plasma, as well as hyper-immune specialty plasma required for manufacturing of our Proprietary Products.

In order for plasma to be used in the manufacturing of our products, the individual centers at which the plasma is collected must be registered with and meet the regulatory requirements of the regulatory authorities, such as the FDA and the EMA, of those countries in which we sell our products. When a new plasma collection center is opened, it must be inspected on an ongoing basis after its approval by the FDA and the EMA for compliance with cGMP and other regulatory requirements, and these regulatory requirements are subject to change. An unsatisfactory inspection could prevent a new center from being established or risk the suspension or revocation of an existing registration. In order for a plasma collection center to maintain its governmental registration, its operations must continue to conform to cGMP and other regulatory requirements or recommendations which may be applicable from time to time (e.g., in January 2022, the FDA issued guidance providing recommendations to blood establishments on collection of convalescent plasma during the public health emergency).

If it would be determined that our plasma collection center did not comply with cGMP, or other regulatory requirements in collecting plasma, we may be unable to use and may ultimately be required to destroy plasma collected from that center, which would be recorded as a charge to cost of goods. Additionally, if noncompliance in the plasma collection process is identified after the impacted plasma has been pooled with compliant plasma from other sources, entire plasma pools, in-process intermediate materials and final products could be impacted. Consequently, we could experience significant inventory impairment provisions and write-offs if it was determined that our plasma collection center did not comply with cGMP in collecting plasma.

We plan to increase our supplies of plasma for use in our manufacturing processes through collections at our plasma collection centers and through the establishment of new plasma collection centers. This strategy is dependent upon our ability to successfully establish and register new centers, to maintain compliance with all FDA and other regulatory requirements in all centers and to attract donors to our centers.

Our ability to increase and improve the efficiency of plasma collection at our current or any future plasma collection center may be affected by: (i) changes in the economic environment and population in selected regions where we operate plasma collection centers; (ii) the entry of competitive centers into regions where we operate; (iii) our misjudging the demographic potential of individual regions where we expect to increase production and attract new donors; (iv) unexpected facility related challenges; (v) unexpected management challenges at select plasma collection centers; or (vi) changes to regulatory requirements.

The biologic properties of plasma and plasma derivatives are variable, which may impact our ability to consistently manufacture our products in accordance with the approved specifications.

While our manufacturing processes were developed to meet certain product specifications, variations in the biologic properties of the plasma or plasma derivatives as well as the manufacturing processes themselves may result in out of specification results during the manufacturing of our products. While we expect certain work-in-process inventories scraps in the ordinary course of business because of the complex nature of plasma and plasma derivatives, our processes and our plasma-derived protein therapeutics, unanticipated events may lead to write-offs and other costs in amounts that are materially higher than our expectations. We have, in the past, experienced situations that have caused us to write-off the value of our products. Such write-offs and other costs could materially adversely affect our operating results.

The biologic properties of plasma and plasma derivatives are variable, which may adversely impact our levels of product yield from our plasma or plasma derivative supply.

Due to the nature of plasma, there will be variations in the biologic properties of the plasma or plasma derivatives we purchase that may result in fluctuations in the obtainable yield of desired fractions, even if cGMP is followed. Lower yields may limit production of our plasma-derived protein therapeutics because of capacity constraints. If these batches of plasma with lower yields impact production for extended periods, we may not be able to fulfill orders on a timely basis and the total capacity of product that we are able to market could decline and our cost of goods sold could increase, thus reducing our profitability.

Usage of our products may lead to serious and unexpected side effects, which could materially adversely affect our business and may, among other factors, lead to our products being recalled and our reputation being harmed, resulting in an adverse effect on our operating results.

The use of our plasma-derived protein therapeutics may produce undesirable side effects or adverse reactions or events. For the most part, these side effects are known, are expected to occur at some frequency and are described in the products' labeling. Known side effects of several plasma-derived therapeutics include headache, nausea and additional common protein infusion related events, such as flu-like symptoms, dizziness and hypertension. The occurrence of known side effects on a large scale could adversely affect our reputation and public image, and hence also our operating results.

In addition, the use of our plasma-derived protein therapeutics may be associated with serious and unexpected side effects, or with less serious reactions at a greater than expected frequency. This may be especially true when our products are used in critically ill patient populations. When these unexpected events are reported to us, we typically make a thorough investigation to determine causality and implications for product safety. These events must also be specifically reported to the applicable regulatory authorities, and in some cases, also to the public by media channels. If our evaluation concludes, or regulatory authorities perceive, that there is an unreasonable risk associated with one of our products, we would be obligated to withdraw the impacted lot or lots of that product or, in certain cases, to withdraw the product entirely. Furthermore, it is possible that an unexpected side effect caused by a product could be recognized only after extensive use of the product, which could expose us to product liability risks, enforcement action by regulatory authorities and damage to our reputation.

We are subject to several existing laws and regulations in multiple jurisdictions, non-compliance with which could adversely affect our business, financial condition and results of operations, and we are susceptible to a changing regulatory environment, which could increase our compliance costs or reduce profit margins.

Any new product must undergo lengthy and rigorous testing and other extensive, costly, and time-consuming procedures mandated by the FDA and similar authorities in other jurisdictions, including the EMA and the regulatory authorities in Israel. Our facilities and those of our contract manufacturers must be approved and licensed prior to production and remain subject to inspection from time to time thereafter. Failure to comply with the requirements of the FDA or similar authorities in other jurisdictions, including a failed inspection or a failure in our reporting system for adverse effects of our products experienced by the users of our products, or any other non-compliance, could result in warning letters, product recalls or seizures, monetary sanctions, injunctions to halt the manufacture and distribution of products, civil or criminal sanctions, import or export restrictions, refusal or delay of a regulatory authority to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. Furthermore, we may experience delays or additional costs in obtaining new approvals or licenses, or extensions of existing approvals and licenses, from a regulatory authority due to reasons that are beyond our control such as changes in regulations or a shutdown of the U.S. federal government, including the FDA, or similar governing bodies or authorities in other jurisdictions. In addition, while we recently entered the U.S. plasma collection market with our recent acquisition of a plasma collection center in the United States, we continue to rely on, Kedrion, CSL Behring, Emergent, Takeda and additional plasma suppliers, for plasma collection required for the manufacturing of KEDRAB, CYTOGAM, HEPGAM B, VARIZIG, WINRHO SDF, GLASSIA and other Proprietary products, and in the case of Kedrion and Takeda, for the distribution of these products in the United States (and in the case of Takeda, also potentially in Canada, Australia and New Zealand). In performing such services for us, these plasma suppliers are required to comply with certain regulatory requirements. Any failure by these plasma suppliers to properly advise us regarding, or properly perform tasks related to, regulatory compliance requirements, could adversely affect us. Any of these actions could cause direct liabilities, a loss in our ability to market each of KEDRAB, CYTOGAM, HEPGAM B, VARIZIG, WINRHO SDF, GLASSIA and/or other Proprietary products, or a loss of customer confidence in us or in our Proprietary products, which could materially adversely affect our sales, future revenues, reputation, and results of operations. Similarly, we rely on other third-party vendors, for example, in the testing, handling, and distributions of our products. If any of these companies incur enforcement action from regulatory authorities due to noncompliance, this could negatively affect product sales, our reputation and results of operations. In addition, we rely on other distributors of our other proprietary products, for purposes of our distribution-related regulatory compliance for the products they distribute in the territories in which they operate. Any failure by such distributors to properly advise us regarding, or properly perform tasks related to, regulatory compliance requirements, could adversely affect our sales, future revenues, reputation and results of operations.

Changes in our production processes for our products may require supplemental submissions or prior approval by FDA and/or similar authorities in other jurisdictions. Failure to comply with any requirements as to production process changes dictated by the FDA or similar authorities in other jurisdictions could also result in warning letters, product recalls or seizures, monetary sanctions, injunctions to halt the manufacture and distribution of products, civil or criminal sanctions, refusal or delay of a regulatory authority to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses.

Pursuant to the amendment to the GLASSIA license agreement with Takeda, entered into in March 2021, upon completion of the transition of GLASSIA manufacturing to Takeda, which was completed in November 2021, we transferred to Takeda the GLASSIA U.S. BLA. Following the effectiveness of such transfer, we will rely on Takeda to share with us any relevant information with respect to changes in the manufacturing of the product or its usage which may be applicable in order to update the products registration file in certain ROW markets in which it is currently registered and/or distributed or may be registered and/or distributed in the future.

In addition, changes in the regulation of our activities, such as increased regulation affecting quality or safety requirements or new regulations such as limitations on the prices charged to customers in the United States, Israel or other jurisdictions in which we operate, could materially adversely affect our business. In addition, the requirements of different jurisdictions in which we operate may become less uniform, creating a greater administrative burden and generating additional compliance costs, which would have a material adverse effect on our profit margins. See also – "*Regulatory approval for our products is limited by the FDA, EMA, the IMOH and similar authorities in other jurisdictions to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, and the prescription or promotion of off-label uses could adversely affect our business.*"; and "*—Laws and regulations governing the conduct of international operations may negatively impact our development, manufacture, and sale of products outside of the United States and require us to develop and implement costly compliance programs." and "—Uncertainty surrounding and future changes to healthcare law in the United States and other United States Government related mandates may adversely affect our business."*

If we experience equipment difficulties or if the suppliers of our equipment or disposable goods fail to deliver key product components or supplies in a timely manner, our manufacturing ability would be impaired, and our product sales could suffer.

For certain equipment and supplies, we depend on a limited number of companies that supply and maintain our equipment and provide supplies such as chromatography resins, filter media, glass bottles and stoppers used in the manufacture of our plasma-derived protein therapeutics. If our equipment were to malfunction, or if our suppliers stop manufacturing or supplying such machinery, equipment or any key component parts, the repair or replacement of the machinery may require substantial time and cost and could disrupt our production and other operations. Alternative sources for key component parts or disposable goods may not be immediately available. In addition, any new equipment or change in supplied materials may require revalidation by us or review and approval by the FDA, the EMA, the IMOH or other regulatory authorities, which may be time-consuming and require additional capital and other resources. We may not be able to find an adequate alternative supplier in a reasonable time period, or on commercially acceptable terms, if at all. As a result, shipments of affected products may be limited or delayed. Our inability to obtain our key source supplies for the manufacture of products may require us to delay shipments of products, harm customer relationships and force us to curtail operations.

We have been required to conduct post-approval clinical trials of GLASSIA and KEDRAB as a commitment to continuing marketing such products in the United States, and we may be required to conduct post-approval clinical trials as a condition to licensing or distributing other products.

When a new product is approved, the FDA or other regulatory authorities may require post-approval clinical trials, sometimes called Phase 4 clinical trials. For example, the FDA has required that we conduct Phase 4 clinical trials of GLASSIA and for KEDRAB. Such Phase 4 clinical trials are aimed at collecting additional safety data, such as the immune response in the body of a human or animal, commonly referred to as immunogenicity, viral transmission, levels of the protein in the lung, or epithelial lining fluid, and certain efficacy endpoints requested by the FDA. If the results of such trials are unfavorable and demonstrate a previously undetected risk or provide new information that puts patients at risk, or if we fail to complete such trials as instructed by the FDA, this could result in receiving a warning letter from the FDA and the loss of the approval to market the product in the United States and other countries, or the imposition of restrictions, such as additional labeling, with a resulting loss of sales. Furthermore, there can be no assurance that the FDA will accept the results of any post-marketing commitment study, such as the results of the KEDRAB study, and under certain circumstances the FDA may require a subsequent study. Other products we develop may face similar requirements, which would require additional resources and which may not be successful. We may also receive approval that is conditioned on successful additional data or clinical development, and failure in such further development may require similar changes to our product label or result in revocation of our marketing authorization.

The nature of producing and developing plasma-derived protein therapeutics may prevent us from responding in a timely manner to market forces and effectively managing our production capacity.

The production of plasma-derived protein therapeutics is a lengthy and complex process. Our ability to match our production of plasma-derived protein therapeutics to market demand is imprecise and may result in a failure to meet the market demand for our plasma-derived protein therapeutics or potentially in an oversupply of inventory. Failure to meet market demand for our plasma-derived protein therapeutics may result in customers transitioning to available competitive products, resulting in a loss of segment share or distributor or customer confidence. In the event of an oversupply in the market, we may be forced to lower the prices we charge for some of our plasma-derived protein therapeutics, record asset impairment charges or take other action which may adversely affect our business, financial condition and results of operations.

Risks Related to Our Distribution Segment

Our Distribution segment is dependent on a few suppliers, and any disruption to our relationship with these suppliers, or their inability to supply us with the products we sell, in a timely manner, in adequate quantities and/or at a reasonable cost, would have a material adverse effect on our business, financial condition and results of operations.

Sales of products supplied by Biotest A.G., Kedrion, Chiesi Farmaceutici S.p.A, BPL and Valneva SE, which are sold in our Distribution segment, together represented approximately 18%, 20% and 26% of our total revenues for the years ended December 31, 2023, 2022 and 2021, respectively. While we have distribution agreements with each of our suppliers, these agreements do not obligate these suppliers to provide us with minimum amounts of our Distribution segment products. Purchases of our Distribution segment products from our suppliers are typically on a purchase order basis. We work closely with our suppliers to develop annual forecasts, but these forecasts are not obligations or commitments. However, if we fail to submit purchase orders that meet our annual forecasts or if we fail to meet our minimum purchase obligations, we could lose exclusivity or, in certain cases, the distribution agreement could be terminated.

These suppliers may experience capacity constraints that result in their being unable to supply us with products in a timely manner, in adequate quantities and/or at a reasonable cost. Contributing factors to supplier capacity constraints may include, among other things, industry or customer demands in excess of machine capacity, labor shortages, changes in raw material flows or shortages in raw materials, which may result from different market conditions including, but not limited to, shortages resulting from increased global demand for these raw materials due to global healthcare issues, epidemics and pandemics. These suppliers may also choose not to supply us with products at their discretion or raise prices to a level that would render our products noncompetitive. Any significant interruption in the supply of these products could result in us being unable to meet the demands of our customers, which would have a material adverse effect on our business, financial condition and results of operations as a result of being required to pay of fines or penalties, be subject to claims of reach of contract, loss of reputation or even termination of agreement.

If our relationship with either distributor deteriorated, our distribution sales could be adversely affected. If we fail to maintain our existing relationships with these suppliers, we could face significant costs in finding a replacement supplier, and delays in establishing a relationship with a new supplier could lead to a decrease in our sales and a deterioration in our market share when compared with one or more of our competitors.

Additionally, our future growth in the Distribution segment is dependent on our ability to successfully engage other manufacturers for distribution in Israel of other products. Failure to engage new suppliers may have an adverse effect on our revenue growth and profitability.

Certain of our sales in our Distribution segment rely on our ability to win tender bids based on the price and availability of our products in annual public tender processes.

Certain of our sales in our Distribution segment rely on our ability to win tender bids during the annual tender process in Israel, as well as on sales made to Health Maintenance Organizations (HMOs), hospitals and to the IMOH. Our ability to win bids may be materially adversely affected by competitive conditions in such bid process. Our existing and new competitors may also have significantly greater financial resources than us, which they could use to promote their products and business. Greater financial resources would also enable our competitors to substantially reduce the price of their products or services. If our competitors are able to offer prices lower than us, our ability to win tender bids during the annual tender process will be materially affected and could reduce our total revenues or decrease our profit margins.

Certain of our products in both segments have historically been subject to price fluctuations as a result of changes in the production capacity available in the industry, the availability and pricing of plasma, development of competing products and the availability of alternative therapies. Higher prices for plasma-derived protein therapeutics have traditionally spurred increases in plasma production and collection capacity, resulting over time in increased product supply and lower prices. As demand continues to grow, if plasma supply and manufacturing capacity do not commensurately expand, prices tend to increase. Additionally, consolidation in plasma companies has led to a decrease in the number of plasma suppliers in the world, as either manufacturers of plasma-based pharmaceuticals purchase plasma suppliers or plasma suppliers are shut down in response to the number of manufacturers of plasma-based pharmaceuticals decreasing, which may lead to increased prices. We may not be able to pass along these increased plasma and plasma-derivative prices to our customers, which would reduce our profit margins.

Sales of our Distribution segment products are made through public tenders of Israeli hospitals and HMOs on an annual basis or in the private market based on detailing activity made by our medical representatives. The prices we can offer, as well as the availability of products, are key factors in the tender process. If our suppliers in the Distribution segment cannot sell us products at a competitive price or cannot guarantee sufficient quantities of products, we may lose the tenders.

Our Distribution segment is dependent on a few customers, and any disruption to our relationship with these customers, or our inability to supply, in a timely manner, in adequate quantities and/or at a reasonable cost, would have a material adverse effect on our business, financial condition and results of operations.

The Israeli market for drug products includes a relatively small number of HMOs and several hospitals. Sales to Clalit Health Services, an Israeli HMO, accounted for approximately 34%, 46% and 42% of our Distribution segment revenues in the years ended December 31, 2023, 2022 and 2021, respectively.

If our relationship with any of our Israeli customers deteriorated, our distribution sales could be adversely affected. Failure to maintain our existing relationships with these customers could lead to a decrease in our revenues and profitability.

Before we may sell products in the Distribution segment, we must register the products with the IMOH and there can be no assurance that such registration will be obtained.

Before we may sell products in the Distribution segment in Israel, we must register the products, at our own expense, with the IMOH. We cannot predict how long the registration process of the IMOH may take or whether any such registration ultimately will be obtained. The IMOH has substantial discretion in the registration process, and we can provide no assurance of success of registration. Our business, financial condition or results of operations could be materially adversely affected if we fail to receive IMOH registration for the products in the Distribution segment.

Our Distribution segment is a low-margin business and our profit margins may be sensitive to various factors, some of which are outside of our control.

Our Distribution segment is characterized by high volume sales with relatively low profit margins. Volatility in our pricing may have a direct impact on our profitability. Prolonged periods of product cost inflation may have a negative impact on our profit margins and results of operations to the extent we are unable to pass on all or a portion of such product cost increases to our customers. In addition, if our product mix changes, we may face increased risks of compression of our margins, as we may be unable to achieve the same level of profit margins as we are able to capture on our existing products. Our inability to effectively price our products or to reduce our expenses due to volatility in pricing could have a material adverse impact on our business, financial condition or results of operations.

We may be subject to milestone payments in connection with our Distribution segment products irrespective of whether the commercialization is successful.

Certain of our agreements in the Distribution segment, including agreements for distribution of biosimilar product candidates, require us to make milestone payments in advance of product launch. In some cases, we may not be able to obtain reimbursement for such payments. To the extent that we are not ultimately able to recoup these payments, our business, financial position and results of operations may be adversely affected.

We face significant competition in our Distribution segment from companies with greater financial resources.

In the Distribution segment, we face competition for our distribution products that are marketed in Israel and compete for market share. We believe that there are several companies active in the Israeli market distributing the products of several manufacturers whose comparable products compete with the products we distribute as part of our Distribution segment. In the plasma area, these manufacturers include Grifols, Takeda and CSL Behring. In other specialties and biosimilar products, we compete with products produced by some of the largest pharmaceutical manufacturers in the world, such as Novartis AG, AstraZeneca AB, Sanofi and GlaxoSmithKline. Each of these competitors sells its products through a local subsidiary or a local representative in Israel. Our existing and new competitors may have significantly greater financial resources than us, which they could use to promote their products and business or reduce the price of their products or services. If we are unable to maintain or increase our market share, we may need to reduce prices and may suffer reduced profitability or operating losses, which could have a material adverse impact on our business, financial condition or results of operations.

In recent years we entered into agreements for future distribution in Israel of several biosimilar product candidates, and the successful future distribution of these products is dependent upon several factors some of which are beyond our control.

Over the past several years we entered into agreements with respect to planned distribution in Israel of certain biosimilar product candidates. Biosimilar products are highly similar to biological products already licensed for distribution by the FDA, EMA or any other relevant regulatory agency, notwithstanding minor differences in clinically inactive components, and that they have no clinically meaningful differences, as compared to the marketed biological products in terms of the safety, purity and potency of the products. The similar nature of a biosimilar and a reference product is demonstrated by comprehensive comparability studies covering quality, biological activity, safety and efficacy.

In order to launch biosimilar products in Israel, we would need to obtain IMOH marketing authorization, which will be subject to prior authorization to be obtained by the manufacturer of the biosimilar product from the FDA or the EMA. Even if an FDA or EMA authorization is provided, there can be no assurance that the IMOH will accept such authorization as a reference and will grant us the authorization to distribute such biosimilar products in the Israeli market. In the event we will not be able to obtain the necessary marking authorization to launch the products, we may not generate the expected sale and profitability from these products, which could have a material adverse impact on our business, financial condition or results of operations. Delays in the commercialization of such biosimilar products, including due to delays in obtaining marketing authorization, may expose us to increased competition, such as due to the entry of new competitors into the market, which may adversely impact our potential sales and profitability from these products.

Innovative pharmaceutical products are generally protected for a defined period by various patents (including those covering drug substance, drug product, approved indications, methods of administration, methods of manufacturing, formulations and dosages) and/or regulatory exclusivity, which are intended to provide their holders with exclusive rights to market the products for the life of the patent or duration of the regulatory data protection period. Biosimilar products are intended to replace such innovative pharmaceutical products upon the expiration or termination of their exclusivity period or in such markets whereby such exclusivity does not exist. The launch of a biosimilar product may potentially result in the infringement of certain IP rights and exclusivity and be subject to potential legal proceedings and restraining orders affecting its potential launch. Such intellectual property threats may preclude commercialization of such biosimilar product candidates, may result in incurring significant legal expenses and liabilities and we may not generate the expected sale and profitability from these products, which could have a material adverse impact on our business, financial condition or results of operations.

In addition, the commercialization of biosimilars includes the potential for steeper than anticipated price erosion due to increased competitive intensity, and lower uptake for biosimilars due to various factors that may vary for different biosimilars (e.g., anti-competitive practices, physician reluctance to prescribe biosimilars for existing patients taking the originator product, or misaligned financial incentives), all of which may affect our potential sales and profitability from these products which could have a material adverse impact on our business, financial condition or results of operations.

Risks Related to Development, Regulatory Approval and Commercialization of Product Candidates

Drug product development including preclinical and clinical trials is a lengthy and expensive process and may not result in receipt of regulatory approval.

Before obtaining regulatory approval for the sale of our product candidates, including Inhaled AAT for AATD, or for the marketing of existing products for new indications, we must conduct, at our own expense, extensive preclinical tests to demonstrate the safety of our product candidates in animals and clinical trials to demonstrate the safety and efficacy of our product candidates in humans. We cannot predict how long the approval processes of the FDA, the EMA, the regulatory authorities in Israel or any other applicable regulatory authority or agency for any of our product candidates will take or whether any such approvals ultimately will be granted. The FDA, the EMA, the regulatory authorities in Israel and other regulatory agencies have substantial discretion in the relevant drug approval process over which they have authority, and positive results in preclinical testing or early phases of clinical studies offer no assurance of success in later phases of the approval process. The approval process varies from country to country and the requirements governing the conduct of clinical trials, product manufacturing, product licensing, pricing and reimbursement vary greatly from country to country.

Preclinical and clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. For example, the Phase 2/3 clinical trial in Europe for Inhaled AAT for AATD did not meet its primary or secondary endpoints and we subsequently withdrew the Marketing Authorization Application ("MAA") in Europe for our Inhaled AAT for AATD.

Each inhaled formulation of AAT, including Inhaled AAT for AATD, is being developed with a specific nebulizer produced by PARI, and the occurrence of an adverse market event or PARI's non-compliance with its obligations would have a material adverse effect on the commercialization of any inhaled formulation of AAT.

We are dependent upon PARI GmbH ("PARI") for the development and commercialization of any inhaled formulation of AAT, including our Inhaled AAT for AATD. We have an agreement with PARI, pursuant to which it is required to obtain the appropriate clearance to market PARI's proprietary eFlow® device, which is a device required for the administration of inhaled formulation of AAT, from the EMA and FDA for use with Inhaled AAT for AATD. See "Item 4. Information on the Company — *Strategic Partnerships — PARI*." Failure of PARI to achieve these authorizations, or to maintain operations in regulatory compliance, will have a material adverse effect on the commercialization of any inhaled formulation of AAT, including Inhaled AAT for AATD, which would harm our growth strategy.

Additionally, pursuant to the agreement, PARI is obligated to manufacture and supply all of the market demand for the eFlow device for use in conjunction with any inhaled formulation of AAT and we are required to purchase all of our volume requirements from PARI. Any event that permanently, or for an extended period, prevents PARI from supplying the required quantity of devices would have an adverse effect on the commercialization of any inhaled formulation of AAT, including Inhaled AAT for AATD.

Lastly, we rely on PARI to ensure that the eFlow device is not violating or infringing on any third party intellectual property or patents. PARI's inability to ensure its freedom to operate may have a significant effect on our ability to continue the development of our Inhaled AAT product candidate as well as potentially commercializing it.

We rely on third parties to conduct our preclinical and clinical trials. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may not obtain regulatory approval for, or commercialize, our product candidates in a timely manner or at all.

We rely upon third-party contractors, such as university researchers, study sites, physicians and contract research organizations ("CROs"), to conduct, monitor and manage data for our current and future preclinical and clinical programs. We expect to continue to rely on these parties for execution of our preclinical and clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on such third-party contractors does not relieve us of our regulatory responsibilities. With respect to clinical trials, we and our CROs are required to comply with current Good Clinical Practices ("GCP"), which are regulations and guidelines enforced by the FDA, the EMA and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements.

These third-party contractors are not our employees, we cannot effectively control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs, and except for remedies available to us under our agreements with such third-party contractors, we may be unable to recover losses that result from any inadequate work on such programs. If such third-party contractors do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our development efforts and clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of such third-party contractors in the future, our business may be adversely affected.

We have initiated the development of a recombinant AAT product candidate; however, any continued development of this product will be dependent on our ability to attract a suitable development/commercialization partner for this project, and we may not be able to successfully complete its development or commercialize such product candidate for numerous reasons.

During 2020, we initiated the development of a recombinant version of AAT, through external services of a contract development and manufacturing organization ("CDMO"). See "Item 4. Information on the Company — *Our Development Product Pipeline — Recombinant AAT.*". The main advantage of recombinant AAT is its potentially wider availability, and ease of large-scale manufacturing. However, continued investment in the development of this product will be subject to identifying a suitable development partner, and we may not be able to identify such a suitable partner or be successful in entering into an agreement with any particular partner on acceptable terms or at all. Further, even if we are successful in entering into an arrangement with such a partner, we may not be able to successfully develop or commercialize a recombinant product for numerous reasons.

We may encounter unforeseen events that delay or prevent us from receiving regulatory approval for our product candidates.

We have experienced unforeseen events that have delayed our ability to receive regulatory approval for certain of our product candidates, and may in the future experience similar or other unforeseen events during, or as a result of, preclinical testing or the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including the following:

- delays may occur in obtaining our clinical materials;
- our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials or to abandon strategic projects;
- the number of patients required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower or more difficult than we anticipate due to various reasons, including challenges that may be imposed as a result of events outside our control (such as a resurgence of the COVID-19 pandemic, which resulted in a significant slow-down in patient recruitment to our on-going Inhaled AAT Phase 3 study), or participants may withdraw from our clinical trials at higher rates than we anticipate;
- delays may occur in reaching agreement on acceptable clinical trial agreement terms with prospective sites or obtaining institutional review board approval;
- our strategic partners may not achieve their clinical development goals and/or comply with their relevant regulatory requirements, which could affect our ability to conduct our clinical trials or obtain marketing authorization;
- we may be forced to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks or if any participant experiences an unexpected serious adverse event;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- regulators may not authorize us to commence or conduct a clinical trial within a country or at a prospective trial site, or according to the clinical trial outline we propose;
- undetected or concealed fraudulent activity by a clinical researcher, if discovered, could preclude the submission of clinical data prepared by that researcher, lead to the suspension or substantive scientific review of one or more of our marketing applications by regulatory agencies, and result in the recall of any approved product distributed pursuant to data determined to be fraudulent;

- the cost of our clinical and preclinical trials may be greater than we anticipate;

- an audit of preclinical tests or clinical studies by the FDA, the EMA, the regulatory authorities in Israel or other regulatory authorities may reveal noncompliance with applicable regulations, which could lead to disqualification of the results of such studies and the need to perform additional tests and studies; and

- our product candidates may not achieve the desired clinical benefits, or may cause undesirable side effects, or the product candidates may have other unexpected characteristics.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we contemplate, if we are unable to successfully complete our clinical trials or other testing, if the results of these trials or tests are not positive or are only modestly positive, or if safety concerns arise, we may:

- be delayed in obtaining regulatory or marketing approval for our product candidates;

- be unable to obtain regulatory and marketing approval for our product candidates;

- decide to halt the clinical trial or other testing;

- be required to conduct additional trials under a conditional approval;

- be unable to obtain reimbursement for our product candidates in all or some countries;

- only obtain approval for indications that are not as broad as we initially intend;

- have the product removed from the market after obtaining marketing approval from the FDA, the EMA, the regulatory authorities in Israel or other regulatory authorities; and

- be delayed in, or prevented from, the receipt of clinical milestone payments from our strategic partners.

Our ability to enroll patients in our clinical trials in sufficient numbers and on a timely basis is subject to several factors, including the size of the patient population, the time of year during which the clinical trial is commenced, the hesitance of certain patients to leave their current standard of care for a new treatment, and the number of other ongoing clinical trials competing for patients in the same indication and eligibility criteria for the clinical trial. In addition, patients may drop out of our clinical trials at any point, which could impair the validity or statistical significance of the trials. Delays in patient enrollment or unexpected drop-out rates may result in longer development times.

Our product development costs will also increase if we experience delays in testing or approvals. There can be no assurance that any preclinical test or clinical trial will begin as planned, not need to be restructured or be completed on schedule, if at all. Because we generally apply for patent protection for our product candidates during the development stage, significant preclinical or clinical trial delays also could lead to a shorter patent protection period during which we may have the exclusive right to commercialize our product candidates, if approved, or could allow our competitors to bring products to market before we do, impairing our ability to commercialize our products or product candidates.

Pre-clinical studies, including studies of our product candidates in animal models of disease, may not accurately predict the result of human clinical trials of those product candidates. In addition, product candidates studied in Phase 1 and 2 clinical trials may be found not to be safe and/or efficacious when studied further in Phase 3 trials. To satisfy FDA or other applicable regulatory approval standards for the commercial sale of our product candidates, we must demonstrate in adequate and controlled clinical trials that our product candidates are safe and effective. Success in early clinical trials, including Phase 1 and 2 trials, does not ensure that later clinical trials will be successful. Initial results from Phase 1 and 2 clinical trials also may not be confirmed by later analysis or subsequent larger clinical trials. Several companies in the pharmaceutical industry, including us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

We may not be able to commercialize our product candidates in development for numerous reasons.

Even if preclinical and clinical trials are successful, we still may be unable to commercialize a product because of difficulties in obtaining regulatory approval for its production process or problems in scaling that process to commercial production. In addition, the regulatory requirements for product approval may not be explicit, may evolve over time and may diverge among jurisdictions and our third-party contractors, such as CROs, may fail to comply with regulatory requirements or meet their contractual obligations to us.

Even if we are successful in our development and regulatory strategies, we cannot provide assurance that any product candidates we may seek to develop or are currently developing, such as Inhaled AAT for AATD, will ever be successfully commercialized. We may not be able to successfully address patient needs, persuade physicians and payors of the benefit of our product, and lead to usage and reimbursement. If such products are not eventually commercialized, the significant expense and lack of associated revenue could materially adversely affect our business.

We may not be able to successfully build and implement a commercial organization or commercialization program, with or without collaborating partners. The scale-up from research and development to commercialization requires significant time, resources, and expertise, which will rely, to a large extent, on third parties for assistance to help us in our efforts. Such assistance includes, but is not limited to, persuading physicians and payors of the benefit of our product to lead to utilization and reimbursement, developing a healthcare compliance program, and complying with post-marketing regulatory requirements.

Research and development efforts invested in our pipeline of specialty and other products may not achieve the expected results.

We must invest increasingly significant resources to develop specialty products through our own efforts and through collaborations with third parties in the form of partnerships or otherwise. The development of specialty pharmaceutical products involves high-level processes and expertise and carries a significant risk of failure. For example, the average time from the pre-clinical phase to the commercial launch of a specialty pharmaceutical product can be 15 years or longer, and involves multiple stages: not only intensive preclinical, clinical and post clinical testing, but also highly complex, lengthy, and expensive regulatory approval processes as well as reimbursement proceedings, which can vary from country to country. The longer it takes to develop a pharmaceutical product, the longer it may take for us to recover our development costs and generate profits, and, depending on various factors, we may not be able to ever recover such costs or generate profits.

During each stage of development, we may encounter obstacles that delay the development process and increase expenses, leading to significant risks that we will not achieve our goals and may be forced to abandon a potential product in which we have invested substantial amounts of time and money. These obstacles may include the following: shortages in the supply of specialty pharmaceutical products for clinical trials; preclinical-study failures; difficulty in enrolling patients in clinical trials; delays in completing formulation and other work needed to support an application for approval; adverse reactions or other safety concerns arising during clinical testing; insufficient clinical trial data to support the safety or efficacy of a product candidate; other failures to obtain, or delays in obtaining, the required regulatory approvals for a product candidate or the facilities in which a product candidate is manufactured; regulatory restrictions which may delay or block market penetration and the failure to obtain sufficient intellectual property rights for our products.

Accordingly, there can be no assurance that the continued development of our Inhaled AAT and any other product candidate will be successful and will result in an FDA and/or EMA approvable indication.

Because of the amount of time and expense required to be invested in augmenting our pipeline of specialty and other products, including the unique know-how which may be required for such purpose, we may seek partnerships or joint ventures with third parties from time to time, and consequently face the risk that some or all of these third parties may fail to perform their obligations, or that the resulting arrangement may fail to produce the levels of success that we are relying on to meet our revenue and profit goals.

We may not obtain orphan drug status for our products, or we may lose orphan drug designations, which would have a material adverse effect on our business.

One of the incentives provided by an orphan drug designation is market exclusivity for seven years in the United States and ten years in the European Union for the first product in a class approved for the treatment of a rare disease. Although several of our products and product candidates, including Inhaled AAT for AATD, have been granted the designation of an orphan drug, we may not be the first product licensed for the treatment of particular rare diseases in the future or our approved indication may vary from that subject to the orphan designation, or our products may not secure orphan drug exclusivity for other reasons. In such cases we would not be able to take advantage of market exclusivity and instead another sponsor would receive such exclusivity.

Additionally, although the marketing exclusivity of an orphan drug would prevent other sponsors from obtaining approval of the same drug compound for the same indication, such exclusivity would not apply in the case that a subsequent sponsor could demonstrate clinical superiority or a market shortage occurs and would not prevent other sponsors from obtaining approval of the same compound for other indications or the use of other types of drugs for the same use as the orphan drug. In the event we are unable to fill demand for any orphan drug, it is possible that the FDA or the EMA may view such unmet demand as a market shortage, which could impact our market exclusivity.

The FDA and the EMA may also, in the future, revisit any orphan drug designation that they have respectively conferred upon a drug and retain the ability to withdraw the relevant designation at any time. Additionally, the U.S. Congress has considered, and may consider in the future, legislation that would restrict the duration or scope of the market exclusivity of an orphan drug, and, thus, we cannot be sure that the benefits to us of the existing statute in the United States will remain in effect. Furthermore, some court decisions have raised questions about FDA's interpretation of the orphan drug exclusivity provisions, which could potentially affect our ability to secure orphan drug exclusivity.

If we lose our orphan drug designations or fail to obtain such designations for our new products and product candidates, our ability to successfully market our products could be significantly affected, resulting in a material adverse effect on our business and results of operations.

The commercial success of the products that we may develop, if any, will depend upon the degree of market acceptance by physicians, patients, healthcare payors, opinion leaders, patients' organizations, and others in the medical community that any such product obtains.

Any products that we bring to the market may not gain market acceptance by physicians, patients, healthcare payors, opinion leaders, patients' organizations and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate material product revenue and we may not sustain profitability. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, some of which are beyond our control, including:

- the prevalence and severity of any side effects;
- the efficacy, potential advantages and timing of introduction to the market of alternative treatments;
- our ability to offer our product candidates for sale at competitive prices;
- relative convenience and ease of administration of our products;
- the willingness of physicians to prescribe our products;
- the willingness of patients to use our products;
- the strength of marketing and distribution support; and
- third-party coverage or reimbursement.

If we are not successful in achieving market acceptance for any new products that we have developed and that have been approved for commercial sale, we may be unable to recover the large investment we will have made and have committed ourselves to making in research and development efforts and our growth strategy will be adversely affected.

In addition, the proposal of or issuance of recommendations by government agencies, physician or patient organizations, or other industry specialists that limit the use or acceptance of a particular product, whether adopted or not, could result in reduced sales of a product.

Risks Related to Our Operations and Industry

Regulatory approval for our products is limited by the FDA, EMA, the IMOH and similar authorities in other jurisdictions to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, and the prescription or promotion of off-label uses could adversely affect our business.

Regulatory approval of our Proprietary and Distribution products is limited to those specific diseases and indications for which our products have been deemed safe and effective by the FDA, EMA, the IMOH or similar authorities in other jurisdictions. In addition to the regulatory approval required for new formulations, any new indication for an approved product also requires regulatory approval. Once we produce a plasma-derived therapeutic, we rely on physicians to prescribe and administer it as the product label directs and for the indications described on the labeling. To the extent off-label uses (i.e., uses and indications not described in the product's labeling as approved by the applicable regulatory authority, as may be prescribed by treating physicians, in their independent medical judgment) become pervasive and produce results such as reduced efficacy or other reported adverse effects, the reputation of our products in the marketplace may suffer. In addition, to the extent off-label uses are associated with reduced efficacy or increases in reported adverse events or negative health outcomes, there could be a decline in our revenues or potential revenues. Furthermore, the off-label use of our products may increase the risk of product liability claims, which are expensive to defend and could divert our management's attention, result in substantial damage awards against us, and harm our reputation.

Furthermore, while physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those approved by regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA, EMA, the IMOH or other regulators. Although regulatory authorities generally do not regulate the behavior of physicians, they do restrict communications by manufacturers on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, failure to follow FDA, OIG, EMA, the IMOH or similar authorities in other jurisdictions rules and guidelines relating to promotion and advertising can lead to other negative consequences that could hurt us, such as the suspension or withdrawal of an approved product from the market, enforcement letters, restrictions on marketing or manufacturing, injunctions and corrective actions. Other regulatory authorities may separately impose penalties including, but not limited to, fines, disgorgement of money, suspension of ongoing clinical trials, refusal to approve pending applications or supplements to approved applications submitted by us; restrictions on our or our contract manufacturers' operations; product seizure or detention, refusal to permit the import or export of products or criminal prosecution.

Regulatory inspections or audits conducted by regulatory bodies and our partners may lead to monetary losses and inability to adequately manufacture or sell our products.

The regulatory authorities, including the FDA, EMA, the IMOH, as well as our partners may, at any time and from time to time, audit or inspect our facilities. Such audits or inspections may lead to disruption of work, and if we fail to pass such audits or inspections, the relevant regulatory authority or partner may require remedial measures that may be costly or time consuming for us to implement and may result in the temporary or permanent suspension of the manufacture, sale and distribution of our products.

Laws and regulations governing the conduct of international operations may negatively impact our development, manufacture, and sale of products outside of the United States and require us to develop and implement costly compliance programs.

We must comply with numerous laws and regulations in Israel and in each of the other jurisdictions in which we operate or plan to operate. The creation and implementation of any required compliance programs is costly, and the programs are often difficult to enforce, particularly where we must rely on third parties.

For example, the U.S. Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from paying, offering, authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also requires companies whose securities are listed in the United States to comply with certain accounting provisions. For example, such companies must maintain books and records that accurately and fairly reflect all transactions of the company, including international subsidiaries, and devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the U.S. Department of Justice, and the U.S. Securities and Exchange Commission (the "SEC") is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA and similar laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered as foreign officials. Additionally, pharmaceutical products are usually marketed by the local distributors through government tenders, and the majority of pharmaceutical companies' clients are HMOs which are foreign government officials under the FCPA. Certain payments to hospitals in connection with clinical trials and other work, and certain payments to HMOs have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. Additionally, the SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

If our manufacturing facility in Beit Kama, Israel were to suffer a serious accident, contamination, force majeure event (including, but not limited to, a war, terrorist attack, earthquake, major fire or explosion etc.) materially affecting our ability to operate and produce saleable plasma-derived protein therapeutics, all of our manufacturing capacity could be shut down for an extended period.

We rely on a single manufacturing facility in Beit Kama, which is located in southern Israel, approximately 20 miles east of the Gaza Strip. A significant part of our revenues in our Proprietary Products segment were derived and are expected to continue to be derived from products manufactured at this facility and some of the products that are imported by us under our Distribution segment, are packed and stored in this manufacturing facility. If this facility were to suffer an accident or a force majeure event such as war, terrorist attack, earthquake, major fire or explosion, major equipment failure or power failure lasting beyond the capabilities of our backup generators or similar event, or contamination, our revenues would be materially adversely affected. In this situation, our manufacturing capacity could be shut down for an extended period, we could experience a loss of raw materials, work in process or finished goods and imported products inventory and our ability to operate our business would be harmed. In addition, in any such event, the reconstruction of our manufacturing facility and storage facilities, and the regulatory approval of the new facilities could be time-consuming. During this period, we would be unable to manufacture our plasma-derived protein therapeutics.

Our insurance against property damage and business interruption insurance may be insufficient to mitigate the losses from any such accident or force majeure event. We may also be unable to recover the value of the lost plasma or work-in-process inventories, as well as the sales opportunities from the products we would be unable to produce or distribute, or the loss of customers during such period.

If our shipping or distribution channels were to become inaccessible due to an accident, act of terrorism, strike, epidemic or pandemic (such as the COVID-19 pandemic) or any other force majeure event, our supply, production and distribution processes could be disrupted.

Most of our Proprietary and Distribution products as well as most of the raw materials we utilize, including plasma and plasma derivatives, must be transported under controlled temperature conditions, including temperature of -20 degrees Celsius (-4 degrees Fahrenheit), to ensure the preservation of their proteins. Not all shipping or distribution channels are equipped to transport products or materials at these temperatures. If any of our shipping or distribution channels become inaccessible because of a serious accident, act of terrorism, strike, epidemic or pandemic (such as the COVID-19 pandemic) or any other force majeure event, we may experience disruptions in continued availability of plasma and other raw materials, delays in our production process or a reduction in our ability to distribute our Proprietary and Distribution products to our customers in the markets in which we operate.

Failure to maintain the security of protected health information or compliance with security requirements could damage our reputation with customers, cause us to incur substantial additional costs and become subject to litigation.

Pursuant to applicable privacy laws, we must comply with comprehensive privacy and security standards with respect to the use and disclosure of protected health information and other personal information. If we do not comply with existing or new laws and regulations related to protecting privacy and security of personal or health information, we could be subject to litigation costs and damages, monetary fines, civil penalties, or criminal sanctions. We may be required to comply with the data privacy and security laws of other countries in which we operate or from which we receive data transfers.

For example, the General Data Protection Regulation ("GDPR") which took effect May 25, 2018, has broad application and enhanced penalties for noncompliance. The GDPR, which is wide-ranging in scope, governs the collection and use of personal data in the European Union and imposes operational requirements for companies that receive or process personal data of residents of the European Union. The GDPR may apply to our clinical development operations. In addition, the Israeli Privacy Protection Regulations (Information Security), 2017, which apply to our operations in Israel, require us to take certain security measures to secure the processing of personal data. Furthermore, U.S. federal and state regulators continue to adopt new, or modify existing laws and regulations addressing data privacy and the collection, processing, storage, transfer and use of data, including the U.S. Health Insurance Portability and Accountability Act of 1996, as amended, and implementing regulations ("HIPAA"). These privacy, security and data protection laws and regulations could impose increased business operational costs, require changes to our business, require notification to customers or workers of a security breach, or restrict our use or storage of personal information. Our efforts to implement programs and controls that comply with applicable data protection requirements are likely to impose additional costs on us, and we cannot predict whether the interpretations of the requirements, or changes in our practices in response to new requirements or interpretations of the requirements, could have a material adverse effect on our business.

We rely upon our CROs, third party contractors and distributors to process personal information on our behalf, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that their activities are conducted in accordance with privacy regulations and our reliance on such CROs, third-party contractors and distributors does not relieve us of our regulatory responsibilities. While we take reasonable and prudent steps to protect personal and health information and use such information in accordance with applicable privacy laws, a compromise in our security systems that results in personal information being obtained by unauthorized persons or our failure to comply with security requirements for financial transactions could adversely affect our reputation with our clients and result in litigation against us or the imposition of penalties, all of which may adversely impact our results of operations, financial condition and liquidity. In addition, given that the privacy laws and regulations in the jurisdictions in which we operate are new and subject to further judicial review and interpretation, it may be determined at a future time that although we take prudent measures to comply with such laws and regulations, such measures will not be sufficient to meet future elaborations or interpretations of such laws and regulations.

If we are unable to successfully introduce new products and indications or fail to keep pace with advances in technology, our business, financial condition and results of operations may be adversely affected.

Our continued growth depends, to a certain extent, on our ability to develop and obtain regulatory approvals of new products, new enhancements and/or new indications for our products and product candidates. Obtaining regulatory approval in any jurisdiction, including from the FDA, EMA or any other relevant regulatory agencies involves significant uncertainty and may be time consuming and require significant expenditures. *See "—Research and development efforts invested in our pipeline of specialty and other products may not achieve expected results."*

The development of innovative products and technologies that improve efficacy, safety, patients' and clinicians' ease of use and cost-effectiveness, involve significant technical and business risks. The success of new product offerings will depend on many factors, including our ability to properly anticipate and satisfy customer needs, adapt to new technologies, obtain regulatory approvals on a timely basis, demonstrate satisfactory clinical results, manufacture products in an economic and timely manner, engage qualified distributors for different territories and establish our sales force to sell our products, and differentiate our products from those of our competitors. If we cannot successfully introduce new products, adapt to changing technologies or anticipate changes in our current and potential customers' requirements, our products may become obsolete and our business could suffer.

Product liability claims or product recalls involving our products, or products we distribute, could have a material adverse effect on our business.

Our business exposes us to the risk of product liability claims that are inherent in the manufacturing, distribution and sale of our Proprietary and Distribution products and other drug products. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and an even greater risk when we commercially sell any products, including those manufactured by others that we distribute in Israel. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, or if the indemnities we have negotiated do not adequately cover losses, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our Proprietary and Distribution products and any product candidates that we may develop;
- injury to our reputation;

- difficulties in recruitment of new participants to our future clinical trials and withdrawal of current clinical trial participants;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- difficulties in finding distributors for our products;
- difficulties in entering into strategic partnerships with third parties;
- diversion of management's attention;
- loss of revenue;
- the inability to commercialize any products that we may develop; and
- higher insurance premiums.

Plasma is biological matter that is capable of transmitting viruses, infections and pathogens, whether known or unknown. Therefore, plasma derivative products, if not properly tested, inactivated, processed, manufactured, stored and transported, could cause serious disease and possibly death to the patient. Further, even when such steps are properly affected, viral and other infections may escape detection using current testing methods and may not be susceptible to inactivation methods. Any transmission of disease through the use of one of our products or third-party products sold by us could result in claims against us by or on behalf of persons allegedly infected by such products.

In addition, we sell and distribute third-party products in Israel, and the laws of Israel could also expose us to product liability claims for those products. Furthermore, the presence of a defect (or a suspicion of a defect) in a product could require us to carry out a recall of such product. A product liability claim or a product recall could result in substantial financial losses, negative reputational repercussions, loss of business and an inability to retain customers. Although we maintain insurance for certain types of losses, claims made against our insurance policies could exceed our limits of coverage or be outside our scope of coverage. Additionally, as product liability insurance is expensive and can be difficult to obtain, a product liability claim could increase our required premiums or otherwise decrease our access to product liability insurance on acceptable terms. In turn, we may not be able to maintain insurance coverage at a reasonable cost and may not be able to obtain insurance coverage that will be adequate to satisfy liabilities that may arise.

Uncertainty surrounding and future changes to healthcare law in the United States and other United States Government related mandates may adversely affect our business.

In the U.S. and in some foreign jurisdictions there has been, and continues to be, significant legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the profitable sale of product candidates. This legislation and regulatory activity have created uncertainty as to whether the industry will continue to experience fundamental change as a result of regulatory reform or legislative reform. There is significant interest among legislators and regulators in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, for example, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected and continues to face major uncertainty due to the status of legislative initiatives surrounding healthcare reform. The Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Reconciliation Act of 2010, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical and healthcare industries. On August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law. The IRA includes several provisions to lower prescription drug costs for people with Medicare and reduce drug spending by the federal government. Implementation of novel and seminal provisions in the IRA related to prescription drug pricing and spending will continue over the next several years and could impact our operations and could have an adverse impact on our ability to generate revenues in the United States.

In the coming years, additional changes could be made to U.S. governmental healthcare programs and U.S. healthcare laws that could significantly impact the success of our products.

In addition, individual states have enacted drug price transparency laws that may impact our decision-making about price increases, including the rate and frequency of such increases. The requirements under these laws vary state-by-state and include obligating manufacturers to provide advance notice of planned price increases, increase amounts and factors considered for those amounts, wholesale acquisition costs, as well as additional information for new drugs. Many states may impose penalties for noncompliance with these requirements, including for failure to report or submission of inaccurate or late reports.

We cannot predict what other legislation relating to our business or to the health care industry may be enacted, or what effect such legislation or other regulatory actions may have on our business, prospects, operating results and financial condition.

The COVID-19 pandemic shined a spotlight on the supply chain for essential medical products, medical countermeasures, and critical inputs to those products and raised legislative and regulatory interest in creating more resiliency in the supply chain, including more domestic manufacturing of essential medical products, medical countermeasures, and critical inputs. There has been significant congressional interest in oversight of pharmaceutical supply chain resiliency as well as a number of legislative proposals to create incentives for domestic manufacturing. There has also been significant executive branch activity to encourage American manufacturing, which may impact FDA-related products. In November 2023, President Biden announced a new White House Council on Supply Chain Resilience to advance a government-wide strategy to build supply chain resilience in critical industries such as essential medical products and countermeasures. As part of that effort, on December 27, 2023, President Biden issued a Presidential Determination under the Defense Production Act (DPA) to enable the Department of Health and Human Services to increase investment in domestic manufacturing of essential medicines, medical countermeasures, and critical inputs deemed as essential to the national defense. In addition, we expect there will continue to be legislative and regulatory efforts to increase domestic manufacturing, including potentially efforts to expedite drug approvals for products that could be competitors to ours. We cannot predict what effect such legislation or regulatory actions, or implementation of the supply chain resiliency measures and DPA authorities, may have on our business, prospects, operating results and financial condition.

Our products and any future approved products remain subject to extensive ongoing regulatory obligations and oversight, including post-approval requirements, that could result in penalties and significant additional expenses and could negatively impact our and our collaborators' ability to commercialize our current and any future approved products.

Any product that has received regulatory approval remains subject to extensive ongoing obligations and continued review from applicable regulatory agencies. These obligations include, among other things, drug safety reporting and surveillance, submission of other post-marketing information and reports, pre-clearance of certain promotional materials, manufacturing processes and practices, product labeling, confirmatory or post-approval clinical research, import and export requirements and record keeping. These obligations may result in significant expense and limit our ability to commercialize our current and any future approved products. Any violation of ongoing regulatory obligations could result in restrictions on the applicable product, including the withdrawal of the applicable product from the market.

If FDA approval is granted via the accelerated approval pathway or a product receives conditional marketing authorization from another comparable regulatory agency, we may be required to conduct a post-marketing confirmatory trial in support of full approval and to comply with other additional requirements. An unsuccessful post-marketing study or failure to complete such a study with due diligence could result in the withdrawal of marketing approval. Post-marketing studies may also suggest unfavorable safety information that could require us to update the product's prescribing information or limit or prevent the product's widespread use. Recent legislation has given the FDA additional authority to require accountability and enforce the post-marketing requirements and commitments associated with accelerated approval.

We and the manufacturers of our current and any future approved products are also required, or will be required, to comply with cGMP, regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory agencies must approve these manufacturing facilities before they can be used to manufacture our products and product candidates, and these facilities are subject to ongoing regulatory inspections. In addition, any approved product, its manufacturer and the manufacturer's facilities are subject to continual regulatory review and inspections, including periodic unannounced inspections. Failure to comply with applicable FDA and other regulatory requirements may subject us to administrative or judicially imposed sanctions and other consequences, including:

- issuance of Form FDA 483 notices or Warning Letters by the FDA or other regulatory agencies;
- imposition of fines and other civil penalties;
- criminal prosecutions;
- injunctions, suspensions or revocations of regulatory approvals;
- suspension of any ongoing clinical trials;
- total or partial suspension of manufacturing;
- delays in regulatory approvals and commercialization;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us;
- refusals to permit drugs to be imported into or exported from the United States;
- restrictions on operations, including costly new manufacturing requirements;
- product recalls or seizures or withdrawal of the affected product from the market; and
- reputational harm.

The policies of the FDA and other regulatory agencies may change and additional laws and regulations may be enacted that could prevent or delay regulatory approval of our product candidates or of our products in any additional indications or territories, or further restrict or regulate post-approval activities. Any problems with a product or any violation of ongoing regulatory obligations could result in restrictions on the applicable product, including the withdrawal of the applicable product from the market. If we are not able to maintain regulatory compliance, we might not be permitted to commercialize our current or any future approved products and our business would suffer.

Laws pertaining to health care fraud and abuse could materially adversely affect our business, financial condition and results of operations.

The laws governing our conduct in the United States are enforceable by criminal, civil, and administrative penalties. Violations of laws such as the Federal False Claims Act (the "FCA"), the Physician Payments Sunshine Act or a provision of the U.S. Social Security Act known as the "federal Anti-Kickback Statute," or any regulations promulgated under their authority may result in jail sentences, fines or exclusion from federal and state health care programs, as may be determined by the Department of Health and Human Services, the Department of Defense, other federal and state regulatory authorities and the federal and state courts. There can be no assurance that our activities will not come under the scrutiny of regulators and other government authorities or that our practices will not be found to violate applicable laws, rules and regulations or prompt lawsuits by private citizen "relators" under federal or state false claims laws.

For example, under the federal Anti-Kickback Statute, and similar state laws and regulations, even common business arrangements, such as discounted terms and volume incentives for customers in a position to recommend or choose drugs and devices for patients, such as physicians and hospitals, can result in substantial legal penalties, including, among others, exclusion from Medicare and Medicaid programs, if those business arrangements are not appropriately structured. Also, a person or company need not have actual knowledge of statute or specific intent to violate certain such laws in order to have committed a violation. Therefore, our arrangements with potential referral sources must be structured with care to comply with applicable requirements. Also, certain business practices, such as payment of consulting fees to healthcare providers, sponsorship of educational or research grants, charitable donations, interactions with healthcare providers that prescribe products for uses not approved by the FDA and financial support for continuing medical education programs, must be conducted within narrowly prescribed and controlled limits to avoid the possibility of wrongfully influencing healthcare providers to prescribe or purchase particular products or as a reward for past prescribing. Manufacturers like us can be held liable under the False Claims Act if they are determined to have caused the submission of false or fraudulent claims to the government for reimbursement. This can result from prohibited activities such as off-label marketing, providing inaccurate billing or coding information to healthcare providers and other customers, or violations of the federal Anti-Kickback Statute Significant enforcement activity has been the result of actions brought by relators, who file complaints in the name of the United States (and if applicable, particular states) under federal and state False Claims Act statutes and can be entitled to receive a significant portion (often as great as 30%) of total recoveries. Also, violations of the False Claims Act can result in treble damages, and each false claim submitted can be subject to a penalty of up to $27,018 per claim. Transfers of value to certain healthcare practitioners and institutions must be tracked and reported in accordance with the Physician Payments Sunshine Act and various state laws. The Physician Payments Sunshine Act imposes reporting and disclosure requirements for pharmaceutical and medical device manufacturers with regard to a broad range of payments, ownership interests, and other transfers of value made to certain physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives and certain teaching hospitals. A number of states have similar laws in place and often require reporting for other categories of healthcare professionals, such as nurses. Additional and stricter prohibitions could be implemented by federal and state authorities. Where practices have been found to involve improper incentives to use products, government investigations and assessments of penalties against manufacturers have resulted in substantial damages and fines. Many manufacturers have been required to enter into consent decrees, corporate integrity agreements, or orders that prescribe allowable corporate conduct. Failure to satisfy requirements under the FDCA can also result in penalties, as well as requirements to enter into consent decrees or orders that prescribe allowable corporate conduct. On November 16, 2020, the U.S. Health and Human Services (HHS) Office of Inspector General (OIG) issued a Special Fraud Alert discussing the fraud and abuse risks associated with payments to physicians related to speaker programs sponsored by pharmaceutical and medical device companies. OIG expressed skepticism regarding the educational value of these industry-sponsored speaker programs and warned of the inherent fraud and abuse risks of these programs.

To market and sell our products outside the United States, we must obtain and maintain regulatory approvals and comply with regulatory requirements in such jurisdictions. The approval procedures vary among countries in complexity and timing. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all, and in such case, we would be precluded from commercializing products in those markets. In addition, some countries, particularly the countries of the European Union, regulate the pricing of prescription pharmaceuticals. In these countries, pricing discussions 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 to other available therapies. Such trials may be time-consuming and expensive and may not show an advantage in cost-efficacy for our products. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, in either the United States or the European Union, we could be adversely affected. Also, under the FCPA, the United States has regulated conduct by U.S. businesses occurring outside of the United States, generally prohibiting remuneration to foreign officials for the purpose of obtaining or retaining business. Additionally, similar to the Physician Payments Sunshine Act, there are legal and regulatory obligations outside the United States that include reporting requirements detailing interactions with and payments to healthcare practitioners. See — General Risks – "*We are subject to risks associated with doing business globally*".

To enhance compliance with applicable health care laws, and mitigate potential liability in the event of noncompliance, regulatory authorities, such as the HHS OIG, have recommended the adoption and implementation of a comprehensive health care compliance program that generally contains the elements of an effective compliance and ethics program described in Section 8B2.1 of the U.S. Sentencing Commission Guidelines Manual. Increasing numbers of U.S.-based pharmaceutical companies have such programs. We have adopted U.S. healthcare compliance and ethics programs that generally incorporate the HHS OIG's recommendations; however, there can be no assurance that following the adoption of such programs we will avoid any compliance issues.

In addition to the federal fraud, waste, and abuse laws noted, there are analogous U.S. state laws and regulations, such as state anti-kickback and false claims laws, and other state laws addressing the medical product and healthcare industries, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and in some cases may apply regardless of payor (i.e., even if reimbursement is not available). Some state laws are constructed in accordance with certain industry voluntary compliance guidelines (e.g., the PhRMA or AdvaMed Codes of Ethics), or the relevant compliance program guidance promulgated by the federal government (HHS-OIG) in addition to other requirements, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Compliance efforts related to such laws are costly, and failure to comply could subject us to enforcement action.

Finally, regulations in both the U.S. and other countries are subject to constant change. There can be no assurance that we can meet the requirements of future regulations or that compliance with current regulations assures future capability to distribute and sell our products.

We could be adversely affected if other government or private third-party payors decrease or otherwise limit the amount, price, scope or other eligibility requirements for reimbursement for the purchasers of our products.

Prices in many of our principal markets are subject to local regulation and certain pharmaceutical products, such as our Proprietary and Distribution products, are subject to price controls. In the United States, where reimbursement levels for our products are substantially established by third-party payors, a reduction in the payors' amount of reimbursement for a product may cause groups or individuals dispensing the product to discontinue administration of the product, to administer lower doses, to substitute lower cost products or to seek additional price-related concessions. These actions could have a negative effect on our financial results, particularly in cases where our products command a premium price in the marketplace or where changes in reimbursement rates induce a shift in the site of treatment. The existence of direct and indirect price controls and pressures over our products has affected, and may continue to materially adversely affect, our ability to maintain or increase gross margins.

Also, the intended use of a drug product by a physician can affect pricing. Physicians frequently prescribe legally available therapies for uses that are not described in the product's labeling and that differ from those tested in clinical studies and approved by the FDA or similar regulatory authorities in other countries. These off-label uses are common across medical specialties, and physicians may believe such off-label uses constitute the preferred treatment or treatment of last resort for many patients in varied circumstances. Reimbursement for such off-label uses may not be allowed by government payors. If reimbursement for off-label uses of products is not allowed by Medicare or other third-party payors, including those in the United States or the European Union, we could be adversely affected. For example, Centers for Medicare and Medicaid ("CMS") could initiate an administrative procedure known as a National Coverage Determination ("NCD"), by which the agency determines which uses of a therapeutic product would be reimbursable under Medicare and which uses would not. This determination process can be lengthy, thereby creating a long period during which the future reimbursement for a particular product may be uncertain.

If we fail to comply with our obligations under U.S. governmental pricing programs, we could be required to reimburse government programs for underpayments and could pay penalties, sanctions, and fines.

In the United States, pricing and reimbursement for our products depend in part on government regulation. Any significant efforts at the federal or state levels to reform the healthcare system by changing the way healthcare is provided or funded or more directly impose controls on drug pricing, government reimbursement, and access to medicines on public and private insurance plans could have a material impact on us. In addition, in order to have our products covered by Medicaid, we must offer discounts or rebates on purchases of pharmaceutical products under various federal and state programs. We also must report specific prices to government agencies. The calculations necessary to determine the prices reported are complex and the failure to do so accurately may expose us to enforcement measures that could negatively affect our results.

We expect to see continued focus by Congress and the Biden Administration on regulating pricing, which could result in legislative and regulatory changes designed to control costs. Changes to the Medicaid program or the federal 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities, could have a material impact on our business. Additional changes to the 340B program are undergoing review and their status is unclear. The Department of Health and Human Services (HHS) has sent letters to numerous manufacturers that have implemented contract pharmacy integrity initiatives expressing the view that their programs are in violation of the 340B statute and referring those programs for potential enforcement action. Several manufacturers have challenged HHS's enforcement letters in federal court and litigation is ongoing in those cases. We believe that our program is consistent with the statute. Additional legal or legislative developments at the federal or state level with respect to the 340B program may have an adverse impact on our integrity initiative, and we may face enforcement action or penalties that could negatively impact our results, depending upon such developments.

We are subject to extensive environmental, health and safety, and other laws and regulations.

Our business involves the controlled use of hazardous materials, various biological compounds and chemicals. 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. In addition, some of the license and permits granted to us may be suspended or revoked, resulting in our inability to conduct our regular business activity, manufacture and/or distribute our products for an extended period of time or until we take remedial actions. 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 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. In addition, fines and penalties may be imposed for noncompliance with environmental, health and safety and other laws and regulations or for the failure to have, or comply with the terms and conditions of, required environmental or other permits or consents. We are subject to future audits by the Environmental Health Department of the Regional Health Bureau of the IMOH and the Ministry of Environmental Protection of Israel and may be required to perform certain actions from time to time in order to comply with these guidelines and their requirements. We do not expect the costs of complying with these guidelines to be material to our business. See "Item 4. Information on the Company — *Environmental*."

Under the Israeli Economic Competition Law, 5758-1988, as amended (the "Competition Law"), a company that supplies or acquires more than 50% of any product or service in Israel in a relevant market may be deemed to be a monopoly. In addition, any company that has "significant market power" (within the meaning of the Competition Law), even if it does not hold market share that is greater than 50%, shall be deemed to be a monopolist under the Competition Law. A monopolist is prohibited from participating in certain business practices, including unreasonably refusing to sell products or provide services over which a monopoly exists, charging unfair prices for such products or services, and abusing its position in the market in a manner that might reduce business competition or harm the public. In addition, the General Director of the Israeli Competition Authority may determine that a company is a monopoly and has the right to order such company to change its conduct in matters that may adversely affect business competition or the public, including by imposing restrictions on its conduct. Depending on the analysis and the definition of the different products we distribute in the markets in which we operate, we may be deemed to be a "monopoly" under the Competition Law with respect to certain of our products. Furthermore, following an amendment to the Competition Law that became effective in August 2015, which repealed the statutory exemption that existed under the Competition Law for restrictive arrangements that were mutually exclusive arrangements, we may face difficulties in certain cases negotiating distribution agreements with foreign pharmaceutical manufacturers.

We have entered into a collective bargaining agreement with the employees' committee and the Histadrut (General Federation of Labor in Israel), and we have incurred and could in the future incur labor costs or experience work stoppages or labor strikes as a result of any disputes in connection with such agreement.

In December 2013, we signed a collective bargaining agreement with the employees' committee established by our employees at our Beit Kama production facility in Israel and the Histadrut (General Federation of Labor in Israel) ("Histadrut"), which expired in December 2017. In November 2018, we signed a further collective bargaining agreement with the employees' committee and the Histadrut, which expired in December 2021. In July 2022, we signed a new collective agreement with the Histadrut; while the agreement will be effective through the end of 2029, certain economic terms may be renegotiated by the parties following the lapse of the four-year anniversary of the agreement. We have experienced labor disputes and work stoppages in the past at our Beit Kama facility. For example, on March 3, 2022, during the course of our negotiations with the Histadrut and the employees' committee on the renewal of the collective bargaining agreement, the employee's committee declared a labor dispute, and on April 26, 2022, a strike was initiated by the employee's committee, which continued until the new agreement was signed in July 2022. As a result of the labor strike, in the year ended December 31, 2022, our gross profit was impacted by a $4.3 million loss associated with the effect of the work-stoppage at the Israeli plant. In addition, in December 2020, during the course of our negotiations with the Histadrut and the employees' committee on severance remuneration for employees who may be laid-off as part of the workforce down-sizing as a result of the transfer of GLASSIA manufacturing to Takeda that we implemented during 2021, the employee's committee declared a labor dispute, which was subsequently concluded during February 2021 following the execution of a special collective bargaining agreement governing such severance terms. In March 2023, we entered into an additional special collective bargaining agreement with the employees' committee and the Histadtrut governing severance remuneration terms for employees who may be laid-off in connection with the potential staff reductions, when needed, in order to adjust to lower plant utilization. Any future disputes with the employees' committee and the Histadrut over the implementation or the interpretation or the renewal of the collective bargaining agreement may lead to additional labor costs and/or work stoppages, which could adversely affect our business operations, including through a loss of revenue and strained relationships with customers.

Following the establishment of our U.S. commercial operations through our subsidiaries Kamada Inc. and Kamada Plasma LLC, we have entered into intercompany agreements for the transfer of products, which require us to meet transfer pricing requirements under both Israeli and U.S. tax legislation.

Following the establishment of our U.S. commercial operations through our subsidiaries Kamada Inc. and Kamada Plasma LLC, we have entered into intercompany agreements for the transfer of products. Our intercompany agreements for the sale of products or provision of services are required to be made on an arms-length basis and must comply with transfer pricing provisions of tax laws in Israel and the U.S. In order to determine the adequate transfer pricing arrangement, we are required to perform a transfer pricing study to compare the contemplated intercompany transaction with similar transactions entered into amongst non-related parties. There can be no assurance that the Israeli and/or tax authorities would accept such transfer pricing study when determining our, or any of our subsidiary's income, profitability and tax assessment. Failure to comply with transfer pricing rules may result in increased tax expenses, penalties and legal actions against us, our subsidiaries or our executive officer.

We may be exposed to tax reporting requirements and tax expense in multiple jurisdictions in which our products are being distributed.

We are incorporated under the laws of the State of Israel and some of our subsidiaries are organized under the laws of Delaware and Ireland and as a result, we are subject to local tax requirements and potential tax expenses in these territories. We store, distribute and sell our Proprietary products in multiple other countries in which we do not have any subsidiaries or physical presence; nevertheless, in some of these countries, pursuant to local legislation, we may be considered as "conducting business activities" which may expose us to certain reporting requirements and potential direct or indirect tax payments. Failure to comply with such local legislation may result in increased tax expenses, penalties and legal actions against us, our subsidiaries or our executive officers.

Risks Related to Intellectual Property

Our success depends in part on our ability to obtain and maintain protection in the United States and other countries for the intellectual property relating to or incorporated into our technology and products, including the patents protecting our manufacturing process.

Our success depends in large part on our ability to obtain and maintain protection in the United States and other countries for the intellectual property covering or incorporated into our technology and products, especially intellectual property related to our manufacturing processes. At present, we consider our patents relating to our manufacturing process to be material to the operation of our business as a whole.

However, the patent landscape in the biotechnology and pharmaceutical fields is highly complicated and uncertain and involves complex legal, factual and scientific questions. Changes in either patent laws or in the interpretation of patent laws in the United States and other countries may diminish the value and strength of our intellectual property or narrow the scope of our patent protection. In addition, we may fail to apply for or be unable to obtain patents necessary to protect our technology or products or enforce our patents due to lack of information about the exact use of our processes by third parties. Even if patents are issued to us or to our licensors, they may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, which could limit our ability to prevent competitors from using similar technology or marketing similar products, or limit the length of time our technologies and products have patent protection. Additionally, many of our patents relate to the processes we use to produce our products, not to the products themselves. In many cases, the plasma-derived products we produce or intend to develop in the future will not, in and of themselves, be patentable. Since many of our patents relate to processes or uses of the products obtained therefrom, if a competitor is able to utilize a process that does not rely on our protected intellectual property, that competitor could sell a plasma-derived product similar to one we have developed or sell it without infringing these patents.

Patent rights are territorial; thus, any patent protections we have will only be enforceable in those countries in which we have issued patents. In addition, the laws of certain countries do not protect our intellectual property rights to the same extent as do the laws of the U.S. and the European Union. Competitors may successfully challenge our patents, produce similar drugs or products that do not infringe our patents, or produce drugs in countries where we have not applied for patent protection or that do not recognize or provide enforcement mechanisms for our patents. Furthermore, it is not possible to know the scope of claims that will be allowed in pending applications or which claims of granted patents, if any, will be deemed enforceable in a court of law.

Due to the extensive time needed to develop, test and obtain regulatory approval for our therapeutic candidates or any product we may sell or market, any patents that protect our therapeutic candidates or any product we may sell or market may expire early during commercialization. This may reduce or eliminate any market advantages that such patents may give us. Following patent expiration, we may face increased competition through the entry of recombinant or generic products into the market and a subsequent decline in market share and profits.

In some cases we may rely on our licensors or partners to conduct patent prosecution, patent maintenance or patent defense on our behalf. Therefore, our ability to ensure that these patents are properly prosecuted, maintained, or defended may be limited, which may adversely affect our rights in our therapeutic candidates and potential approved for marketing products. Any failure by our licensors or development or commercialization partners to properly conduct patent prosecution, maintenance, enforcement, or defense could materially harm our ability to obtain suitable patent protection covering our therapeutic candidates or products or ensure freedom to commercialize the products in view of third-party patent rights, thereby materially reducing our potential profits.

Our patents also may not afford us protection against competitors or other third parties with similar technology. Because patent applications worldwide are typically not published until 18 months after their filing, and because publications of discoveries in scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to file for protection of the inventions set forth in such patent applications. As a result, the patents we own and license may be invalidated in the future, and the patent applications we own and license may not be granted. Moreover, in the US, during 2012, the Leahy-Smith America Invents Act ("AIA") created a new legal proceeding, the *inter partes review* petition, that allows third parties to challenge the validity of patents before the Patent Trials and Appeals Board.

The costs of these proceedings could be substantial and our efforts in them could be unsuccessful, resulting in a loss of our anticipated patent position. In addition, if a third party prevails in such a proceeding and obtains an issued patent, we may be prevented from practicing technology or marketing products covered by that patent. Additionally, patents and patent applications owned by third parties may prevent us from pursuing certain opportunities such as entering into specific markets or developing or commercializing certain products or reducing the cost effectiveness of the relevant business as a result of needing to make royalty payments or other business conciliations. Finally, we may choose to enter into markets where certain competitors have patents or patent protection over technology that may impede our ability to compete effectively.

Our patents are due to expire at various dates between 2024 and 2043. However, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting advantages of the patent. Our pending and future patent applications may not lead to the issuance of patents or, if issued, the patents may not be issued in a form that will provide us with any competitive advantage. We also cannot guarantee that: any of our present or future patents or patent claims or other intellectual property rights will not lapse or be invalidated, circumvented, challenged or abandoned; our intellectual property rights will provide competitive advantages or prevent competitors from making or selling competing products; our ability to assert our intellectual property rights against potential competitors or to settle current or future disputes will not be limited by our agreements with third parties; any of our pending or future patent applications will be issued or have the coverage originally sought; our intellectual property rights will be enforced in jurisdictions where competition may be intense or where legal protection may be weak; or we will not lose the ability to assert our intellectual property rights against, or to license our technology to, others and collect royalties or other payments. In addition, our competitors or others may design around our patents or protected technologies. Effective protection of our intellectual property rights may also be unavailable, limited or not applied in some countries, and even if available, we may fail to pursue or obtain necessary intellectual property protection in such countries. In addition, the legal systems of certain countries do not favor the aggressive enforcement of patents and other intellectual property rights, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In order to preserve and enforce our patent and other intellectual property rights, we may need to make claims, apply certain patent or other regulatory procedures or file lawsuits against third parties. Such proceedings could entail significant costs to us and divert our management's attention from developing and commercializing our products. Lawsuits may ultimately be unsuccessful, and may also subject us to counterclaims and cause our intellectual property rights to be challenged, narrowed, invalidated or held to be unenforceable.

Additionally, unauthorized use of our intellectual property may have occurred or may occur in the future, including, for example, in the production of counterfeit versions of our products. Counterfeit products may use different and possibly contaminated sources of plasma and other raw materials, and the purification process involved in the manufacture of counterfeit products may raise additional safety concerns, over which we have no control. Although we have taken steps to minimize the risk of unauthorized uses of our intellectual property, including for the production of counterfeit products, any failure to identify unauthorized use of, and otherwise adequately protect, our intellectual property could adversely affect our business, including reducing the demand for our products. Additionally, any reported adverse events involving counterfeit products that purported to be our products could harm our reputation and the sale of our products in particular and consumer willingness to use plasma-derived therapeutics in general. Moreover, if we are required to commence litigation related to unauthorized use, whether as a plaintiff or defendant, such litigation would be time-consuming, force us to incur significant costs and divert our attention and the efforts of our management and other employees, which could, in turn, result in lower revenue and higher expenses.

In addition to patented technology, we rely on our unpatented proprietary technology, trade secrets, processes and know-how.

We rely on proprietary information (such as trade secrets, know-how and confidential information) to protect intellectual property that may not be patentable, or that we believe is best protected by means that do not require public disclosure. We generally seek to protect this proprietary information by entering into confidentiality agreements, or consulting, services, material transfer agreements or employment agreements that contain non-disclosure and non-use provisions, as well as ownership provisions, with our employees, consultants, service providers, contractors, scientific advisors and third parties. However, we may fail to enter into the necessary agreements, and even if entered into, these agreements may be breached or otherwise fail to prevent disclosure, third-party infringement or misappropriation of our proprietary information, may be limited as to their term and may not provide an adequate remedy in the event of unauthorized disclosure or use of proprietary information. We have limited control over the protection of trade secrets used by our third-party manufacturers, suppliers, other third parties which are granted with license to use our know-how and former employees and could lose future trade secret protection if any unauthorized disclosure of such information occurs. In addition, our proprietary information may otherwise become known or be independently developed by our competitors or other third parties. To the extent that our employees, consultants, service providers, contractors, scientific advisors and other third parties use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain protection for our proprietary information could adversely affect our competitive business position. Furthermore, laws regarding trade secret rights in certain markets where we operate may afford little or no protection to our trade secrets.

We also rely on physical and electronic security measures to protect our proprietary information, but we cannot provide assurance that these security measures will not be breached or provide adequate protection for our property. There is a risk that third parties may obtain and improperly utilize our proprietary information to our competitive disadvantage. We may not be able to detect or prevent the unauthorized use of such information or take appropriate and timely steps to enforce our intellectual property rights. See "*—Our business and operations would suffer in the event of computer system failures, cyber-attacks on our systems or deficiency in our cyber security measures*."

Changes in either U.S. or foreign patent law or in the interpretation of such laws could diminish the value of patents in general, thereby impairing our ability to protect our products.

Our success, like the success of many other biotechnology companies, is heavily dependent on intellectual property and on patents in particular. The procurement and enforcement of patents in the biotechnology industry is complex from a technological and legal standpoint, and the process is therefore costly, time-consuming and inherently uncertain. In addition, on September 16, 2011, the AIA was signed into law. The AIA included a number of significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application with the United States Patent and Trademark Office ("USPTO") after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. As a result of this change of law, if we do not promptly file a patent application at the time of a new product's invention, and if a third party subsequently invented and patented such product, we would lose our right to patent such invention.

The AIA also introduced new limitations on where a patentee may file a patent infringement suit and new opportunities for third parties to challenge any issued patent in the USPTO. Such changes apply to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard necessary to invalidate a patent claim in USPTO proceedings compared to the evidentiary standard in U.S. federal court, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Depending on decisions by the U.S. Congress, federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents and enforce our existing and future patents.

We may be subject to claims that we infringe, misappropriate or otherwise violate the intellectual property rights of third parties.

The conduct of our business, our Proprietary and/or Distribution products or product candidates may infringe or be accused of infringing one or more claims of an issued patent or may fall within the scope of one or more claims in a published patent application that may be subsequently issued and to which we do not hold a license or other rights. For example, certain of our competitors and other third parties own patents and patent applications in the realm of our biosimilars distribution products, or in areas relating to critical aspects of our business and technology, including the separation and purification of plasma proteins, the composition of AAT, the use of AAT for different indications, and the distribution or use of recombinant or biosimilar pharmaceutical products, and these competitors may in the future allege that we are infringing on their patent rights. We may also be subject to claims that we are infringing, misappropriating or otherwise violating other intellectual property rights, such as trademarks, copyrights or trade secrets. Third parties could therefore bring claims against us or our strategic partners that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if such a claim were brought against us, our strategic partners or our manufacturer suppliers for Distribution products, we or they could be forced to permanently or temporarily stop or delay manufacturing, exportation or sales of such product or product candidate that is the subject of the dispute or suit. See also "*In recent years we entered into agreements for future distribution in Israel of several biosimilar product candidates, and the successful future distribution of these products is dependent upon several factors some of which are beyond our control."*

In addition, we are a party to certain license agreements that may impose various obligations upon us as a licensee, including the obligation to bear the cost of maintaining the patents subject to the license and to make milestone and royalty payments. If we fail to comply with these obligations, the licensor may terminate the license, in which event we might not be able to market any product that is covered by the licensed intellectual property.

If we are found to be infringing, misappropriating or otherwise violating the patent or other intellectual property rights of a third party, or in order to avoid or settle claims, we or our strategic partners may choose or be required to seek a license, execute cross-licenses or enter into a covenant not to sue agreement from a third party and be required to pay license fees or royalties or both, which could be substantial. These licenses may not be available on acceptable terms, or at all. Even if we or our strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened claims, we or our strategic partners are unable to enter into licenses on acceptable terms.

There have been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition, to the extent that we gain greater visibility and market exposure as a public company in the United States, we face a greater risk of being involved in such litigation. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, opposition, cancellation, re-examination and similar proceedings before the USPTO and its foreign counterparts and other regulatory authorities, regarding intellectual property rights with respect to our products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace or to conduct our business in accordance with our plans and budget, and patent litigation and other proceedings may also absorb significant management time.

Some of our employees, consultants and service providers, were previously employed or hired at universities, medical institutes, or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. While we take steps to prevent them from using the proprietary information or know-how of others in their work for us, we may be subject to claims that we or they have inadvertently or otherwise used or disclosed intellectual property, trade secrets or other proprietary information of any such employee's former employer or former ordering service or that they have breached certain non-compete obligations to their former employers. Litigation may be necessary to defend against these claims and, even if we are successful in defending ourselves, could result in substantial costs to us or be distracting to our management. If we fail to defend any such claims successfully, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel.

If we are unable to protect our trademarks from infringement, our business prospects may be harmed.

We own trademarks that identify certain of our products, our business name and our logo, and have registered these trademarks in certain key markets. Although we take steps to monitor the possible infringement or misuse of our trademarks, it is possible that third parties may infringe, dilute or otherwise violate our trademark rights. Any unauthorized use of our trademarks could harm our reputation or commercial interests. In addition, our enforcement against third-party infringers or violators may be unduly expensive and time-consuming, and the outcome may be an inadequate remedy. Even if trademarks are issued to us or to our licensors, they may be challenged, narrowed, cancelled, or held to be unenforceable or circumvented.

Risks Related to Our Financial Position and Capital Resources

We have incurred significant losses since our inception and while we were profitable in the year ended December 31, 2023 and the two years ended December 31, 2020, we incurred operating losses in the 2022 and 2021 fiscal years and may not be able to sustain profitability.

As of December 31, 2023, our cash and cash equivalents were $55.6 million. Since inception, we have incurred significant operating losses, and while we were profitable in the year ended December 31, 2023 and the two years ended December 31, 2020, we incurred net losses of $2.3 million and $2.2 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2023, we had an accumulated deficit of $40.2 million.

The acquisition of the portfolio of four FDA-approved products in November 2021 resulted in the recognition of significant balances of intangible assets as well as contingent consideration and other long-term liabilities. The recognized value of the intangible assets is amortized over their expected useful life, resulting in significant amortization expenses captured as costs of goods sold and sales and marketing expenses. For each of the years ended December 31, 2023 and 2022, such amortization expenses totaled $7.1 million. The contingent consideration and other long-term liabilities are reevaluated at the end of each reporting period resulting in significant revaluation cost recognized as financial expenses. For the years ended December 31, 2023 and 2022, such financial expenses totaled $1.0 million and $6.3 million, respectively. We estimate to incur these significant amortization and financial expenses for the foreseeable future. For additional information, see Note 5b in our consolidated financial statements included in this Annual Report.

While the acquisition of our portfolio of four FDA-approved plasma-derived hyperimmune commercial products represented an important growth driver and revenue source, there can be no assurance that we will be able to continue to reap the benefits of such acquisition and we may not be able to generate or sustain profitability in future years.

Our financial position and operations may be affected as a result of the indebtedness we may incur and the liabilities we assumed in connection with the recent acquisition of the portfolio of four FDA-approved products.

On November 15, 2021, to partially fund the acquisition of the portfolio of four FDA-approved products, we obtained a $40 million debt facility from Bank Hapoalim B.M., comprised of a $20 million short-term revolving credit facility and a $20 million five-year loan. In September 2023, we repaid in full the outstanding balance of the $20 million five-year loan. The credit facility was in effect for an initial period of 12 months, and effective as of January 1, 2023, the credit facility was reduced to NIS 35 million (approximately $10 million) and extended for an additional period of 12 months and subsequently on January 1, 2024, it was extended for an additional period of 12 months. Borrowings under the amended credit facility accrue interest at a rate of PRIME + 0.55 and are repayable no later than 12 months from the date advanced. We are required to pay Bank Hapoalim an annual fee of 0.275% for the credit allocation.

While we have not borrowed money under the credit facility to date, borrowings under the credit facility may have adverse consequences on our business, including:

- expose us to the risk of increased interest rates as these borrowings are subject to the Secured Overnight Financing Rate ("SOFR"), of PRIME + 0.55;
- prevent us from pledging our assets as collateral, which could limit our ability to obtain additional debt financing;
- place us at a competitive disadvantage compared to our competitors that have less debt, better debt servicing options or stronger debt servicing capacity; and
- increase our cost of borrowing.

In addition, the terms of the credit facility contain restrictive covenants that may limit our ability to engage in activities that may be in our long-term best interest. These restrictive covenants include, among others, limitations on restructuring, the sale of purchase of assets, material licenses, certain changes of control and the creation of floating charges over our property and assets. Under the terms of these facilities, we are also required to maintain certain financial covenants, including minimum equity capital, maximum working capital to debt ratio and minimum debt coverage ratio. Our failure to comply with those covenants could result in an event of default which, if not cured or waived, could result in the acceleration of substantially all of our debt.

In addition, as part of the acquisition of the portfolio of four FDA-approved products, we agreed to pay and assumed the following liabilities:

- Up to $50 million of contingent consideration subject to achievement of sales thresholds through December 31, 2034. As of December 31, 2023, the Company had paid the first milestone payment on account of the contingent consideration and the second sales threshold had been met, and the second milestone payment on account of the contingent consideration was paid during February 2024.
- A total amount of $14.2 million on account of acquired inventory to be paid in ten equal quarterly instalments of $1.5M each (or the remaining balance at the final instalment). As of December 31, 2023, we had paid all but the last two instalments, which will be paid during the first half of 2024.
- Future payment of royalties (some of which are perpetual) and milestone payments to third parties subject to the achievement of corresponding CYTOGAM related net sales thresholds and milestones.

The future payments of such obligations may have a significant effect on our cash availability in future periods and may potentially require us to assume more debt. For additional information, see Note 5b in our consolidated financial statements included in this Annual Report.

Our business requires substantial capital, including potential investments in large capital projects, to operate and grow and to achieve our strategy of realizing increased operating leverage, for which we may incur debt or issue additional equity.

In order to obtain and maintain FDA, EMA and other regulatory approvals for product candidates and new indications for existing products, we may be required to enhance the facilities and processes by which we manufacture existing products, to develop new product delivery mechanisms for existing products, to develop innovative product additions and to conduct clinical trials. We face a number of obstacles that we will need to overcome in order to achieve our operating goals, including but not limited to the successful development of experimental products for use in clinical trials, the design of clinical study protocols acceptable to the FDA, the EMA and other regulatory authorities, the successful outcome of clinical trials, scaling our manufacturing processes to produce commercial quantities or successfully transition technology, obtaining FDA, EMA and other regulatory approvals of the resulting products or processes and successfully marketing an approved or new product with applicable new processes. To finance these various activities, we may need to incur debt or issue additional equity. We may not be able to structure our debt obligations on favorable economic terms and any offering of additional equity would result in a dilution of the equity interests of our current shareholders. To the extent that we raise additional funds to fund our activities through debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates, or grant licenses on terms that are not favorable to us. A failure to fund these activities may harm our growth strategy, competitive position, quality compliance and financial condition.

In addition, our manufacturing facility requires continued investment and upgrades. Moreover, any enhancements to our manufacturing facilities necessary to obtain FDA or EMA approval for product candidates or new indications for existing products could require large capital projects. We may also undertake such capital projects in order to maintain compliance with cGMP or expand capacity. Capital projects of this magnitude involve technology and project management risks. Technologies that have worked well in a laboratory or in a pilot plant may cost more or not perform as well, or at all, in full scale operations. Projects may run over budget or be delayed. We cannot be certain that any such project will be completed in a timely manner or that we will maintain our compliance with cGMP, and we may need to spend additional amounts to achieve compliance. Additionally, by the time multi-year projects are completed, market conditions may differ significantly from our initial assumptions regarding competitors, customer demand, alternative therapies, reimbursement and public policy, and as a result capital returns may not be realized. In addition, to fund large capital projects, we may similarly need to incur debt or issue additional dilutive equity. A failure to fund these activities may harm our growth strategy, competitive position, quality compliance and financial condition.

Our current working capital may not be sufficient to complete our research and development with respect to any or all of our pipeline products or to commercialize our products.

As of December 31, 2023, we had cash and cash equivalents of $55.6 million. We plan to fund our future operations through continued sale and distribution of our proprietary and distribution products, commercialization and or out-licensing of our pipeline product candidates, and as requires raising additional capital through the sale of equity or debt. These amounts may not be sufficient to complete the research and development of all of our candidates, and there can be no assurances of the financial success of our commercialization activities or our ability to access the equity and debt capital markets on terms acceptable to us, if at all. To the extent we are unable to fund our research and development, our future product development activities could be materially adversely affected.

We are subject to foreign currency exchange risk.

We receive payment for our sales and make payments for resources in a number of different currencies. While our sales and expenses are primarily denominated in U.S. dollars, our financial results may be adversely affected by fluctuations in currency exchange rates as a portion of our sales and expenses are denominated in other currencies, including the NIS and the Euro. Market volatility and currency fluctuations may limit our ability to cost-effectively hedge against our foreign currency exposure and, in addition, our ability to hedge our exposure to currency fluctuations in certain emerging markets may be limited. Hedging strategies may not eliminate our exposure to foreign exchange rate fluctuations and may involve costs and risks of their own, such as devotion of management time, external costs to implement the strategies and potential accounting implications. Foreign currency fluctuations, independent of the performance of our underlying business, could lead to materially adverse results or could lead to positive results that are not repeated in future periods.

Events in global credit markets may impact our ability to obtain financing or increase the cost of future financing, including interest rate fluctuations based on macroeconomic conditions that are beyond our control.

During periods of volatility and disruption in the U.S., European, Israeli or global credit markets, obtaining additional or replacement financing may be more difficult and the cost of debt could be high. The high cost of debt may limit our ability to have cash on hand for working capital, capital expenditures and acquisitions on terms that are acceptable to us.

To service any future indebtedness and other obligations, we may require a significant amount of cash and our ability to generate cash depends on many factors beyond our control.

The capability to pay and refinance any future indebtedness and to fund working capital requirements and planned capital expenditures will depend on our ability to generate cash in the future. A significant reduction in our operating cash flows resulting from changes in economic conditions, increased competition or other events beyond our control could increase the need for additional or alternative sources of liquidity and could have a material adverse effect on our business, financial condition, results of operations, prospects and our ability to service any future debt and other obligations. If we are unable to service any future indebtedness through sufficient cash flows from operations, we will be forced to shift to alternative strategies, which may include the reducing of capital expenditures, the sale of assets, the restructuring or refinancing of debt (if any) or the seeking of additional equity. We cannot assure that these alternative strategies, if any, could be implemented on satisfactory and commercially reasonable terms, that they would provide sufficient funds to make the required payments on our debt or to fund our other liquidity needs.

Risks Related to Our Ordinary Shares

The requirements of being a public company in the United States, as well as in Israel, may strain our resources and distract our management, which could make it difficult to manage our business and could have a negative effect on our results of operations and financial condition.

As a public company whose shares are traded on the Nasdaq Global Select Market ("Nasdaq") and the Tel Aviv Stock Exchange (the "TASE"), we are required to comply with various regulatory and reporting requirements, including those required by the SEC. Complying with these reporting and regulatory requirements is time consuming, and may result in increased costs to us and could have a negative effect on our business, results of operations and financial condition. As a public company in the United States, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and the requirements of the Sarbanes-Oxley Act of 2002 ("SOX"). These requirements may place a strain on our systems and resources. The Exchange Act requires that we file annual and current reports, and file or make public certain additional information, with respect to our business and financial condition. SOX requires that we maintain effective disclosure controls and procedures and internal controls over financial reporting. To maintain and improve the effectiveness of our disclosure controls and procedures, we may need to commit significant resources, hire additional staff and provide additional management oversight. These activities may divert management's attention from other business concerns, which could have a material adverse effect on our business, financial condition and results of operations. Furthermore, as our business changes and if we expand either through acquisitions or by means of organic growth, our internal controls may become more complex and we will require significantly more resources to ensure our internal controls remain effective. Failure to implement required new or improved controls, or difficulties encountered in their implementation, could impact our financial information and adversely affect our operating results or cause us to fail to meet our reporting obligations. If we identify material weaknesses, the disclosure of that fact, even if quickly remediated, could require significant resources to remediate, expose us to legal or regulatory proceedings, and reduce the market's confidence in our financial statements and negatively affect our share price.

Our share price may be volatile.

The market price of our ordinary shares is highly volatile and could be subject to wide fluctuations in price as a result of various factors, some of which are beyond our control. These factors include:

- actual or anticipated fluctuations in our financial condition and operating results;
- overall conditions in the specialty pharmaceuticals market;
- loss of significant customers or changes to agreements with our strategic partners;
- changes in laws or regulations applicable to our products;
- actual or anticipated changes in our growth rate relative to our competitors';
- announcements of clinical trial results, technological innovations, significant acquisitions, strategic alliances, joint ventures or capital commitments by us or our competitors;
- changes in key personnel;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- the issuance of new or updated research reports by securities analysts;
- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain intellectual property protection for our technologies;
- announcement of, or expectation of, additional financing efforts;
- sales of our ordinary shares by us or our shareholders;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- recalls and/or adverse events associated with our products; and
- general political, economic and market conditions.

Furthermore, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market price of equity securities of many companies. Broad market and industry fluctuations, as well as general economic, political and market conditions, may negatively impact the market price of our ordinary shares.

In the past, companies that have experienced volatility in the market price of their shares have been subject to securities class action litigation or derivative actions. We, as well as our directors and officers, may also be the target of these types of litigation and actions in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

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 shares, our share price and trading volume could be negatively impacted.

The trading market for our ordinary shares may be influenced by the research and reports that industry or securities analysts may 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, if they do, provide favorable coverage. If any of the analysts who may cover us adversely change their recommendation regarding our shares, or provide more favorable relative recommendations about our competitors, our share price 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 our share price or trading volume.

Our shareholders may experience significant dilution as a result of any additional financing using our equity securities or may experience a decrease in the share price due to sales of our equity securities.

To the extent that we raise additional funds to fund our activities through the sale of equity or securities that are convertible into or exchangeable for, or that represent the right to receive, ordinary shares or substantially similar securities, your ownership interest will be diluted. Any additional capital raised through the sale of equity securities will likely dilute the ownership percentage of our shareholders. For example, in September 2023, we consummated a $60.0 million private placement of approximately 12.6 million ordinary shares to FIMI Opportunity Funds.

Future sales of ordinary shares by affiliates could cause our share price to fall.

The FIMI Opportunity Funds collectively own 22,084,287 of our outstanding ordinary shares (representing an ownership percentage of 38.4% of the outstanding shares and 38.3% on a fully diluted basis as of March 1, 2024). Pursuant to a registration rights agreement entered into with FIMI Opportunity Funds on January 20, 2020, as amended on May 23, 2023, they have "demand" and "piggyback" registration rights covering the ordinary shares of our company held by them. All shares of FIMI Opportunity Funds sold pursuant to an offering covered by a registration statement would be freely transferable. Sales of a substantial number of shares of our ordinary shares, or the perception that the FIMI Opportunity Funds may exercise their registration rights, could put downward pressure on the market price of our ordinary shares and could impair our future ability to raise capital through an offering of our equity securities.

The significant share ownership positions and board representation of the FIMI Opportunity Funds and Leon Recanati may limit our shareholders' ability to influence corporate matters.

The FIMI Opportunity Funds (three of whose partners are members of our board of directors, one of which serves as our chairman) and Leon Recanati, a member of our board of directors, beneficially owned, directly and indirectly, approximately 38.4% and 6.2% of our outstanding ordinary shares, respectively, as of March 1, 2024. For additional information, see "Item 6. Directors, Senior Management and Employees — *Share Ownership*" and "*Item 7. Major Shareholders and Related Party Transactions — Major Shareholders*." Accordingly, the FIMI Opportunity Funds and Leon Recanati, through their equity ownership and board representation, individually and collectively, have significant influence over the outcome of matters required to be submitted to our shareholders for approval, including decisions relating to the election of directors (other than our external directors, for whose election the approval of the majority of shares held by non-controlling shareholders and non-interested shareholders is required under Israeli law) and the outcome of any proposed acquisition, merger or consolidation of our company. Their interests may not be consistent with those of our other shareholders. In addition, these parties' significant interest in us may discourage third parties from seeking to acquire control of us, which may adversely affect the market price of our shares. This concentration of ownership may also cause a decrease in the volume of trading or otherwise adversely affect our share price.

On March 6, 2013, a shareholders agreement was entered into, effective March 4, 2013, pursuant to which Mr. Recanati and any company controlled by him (collectively, the "Recanati Group"), on the one hand, and Damar Chemicals Inc. ("Damar"), TUTEUR S.A.C.I.F.I.A ("Tuteur") (companies controlled by the Hahn family) and their affiliates (collectively, the "Damar Group"), on the other hand, have each agreed to vote the ordinary shares beneficially owned by them in favor of the election of director nominees designated by the other group as follows: (i) three director nominees, so long as the other group beneficially owns at least 7.5% of our outstanding share capital, (ii) two director nominees, so long as the other group beneficially owns at least 5.0% (but less than 7.5%) of our outstanding share capital, and (iii) one director nominee, so long as the other group beneficially owns at least 2.5% (but less than 5.0%) of our outstanding share capital. In addition, to the extent that after the designation of the foregoing director nominees there are additional director vacancies, each of the Recanati Group and Damar Group have agreed to vote the ordinary shares beneficially owned by them in favor of such additional director nominees designated by the party who beneficially owns the larger voting rights in our company. We are not party to such agreement or bound by its terms. As a result of such voting agreement, the Recanati Group and the Damar Group and their affiliates together have significant influence over the election of directors of the company.

Our ordinary shares are traded on more than one market and this may result in price variations.

Our ordinary shares have been traded on the TASE since August 2005, and on Nasdaq since May 2013. Trading in our ordinary shares on these markets takes place in different currencies (U.S. dollars on Nasdaq and NIS on the TASE), and at different times (as a result of different time zones, trading days and public holidays in the United States and Israel). The trading prices of our ordinary shares on these two markets may differ due to these and other factors. Any decrease in the price of our ordinary shares on the TASE could cause a decrease in the trading price of our ordinary shares on Nasdaq, and a decrease in the price of our ordinary shares on Nasdaq could likewise cause a decrease in the trading price of our ordinary shares on the TASE.

Our U.S. shareholders may suffer adverse tax consequences if we are characterized as a passive foreign investment company.

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, we would be characterized as a passive foreign investment company ("PFIC") for U.S. federal income tax purposes. If we are characterized as a PFIC, our U.S. shareholders may suffer adverse tax consequences, including having gains realized on the sale of our ordinary shares treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares, and having interest charges apply to distributions by us and the proceeds of share sales. See *"*Item 10. Additional Information — *E. Taxation — United States Federal Income Taxation."*

We are a "foreign private issuer" and have disclosure obligations that are different from those of U.S. domestic reporting companies. As a result, we may not provide you the same information as U.S. domestic reporting companies or we may provide information at different times, which may make it more difficult for you to evaluate our performance and prospects.

We are a foreign private issuer and, as a result, are not subject to the same requirements as U.S. domestic issuers. Under the Exchange Act, we are subject to reporting obligations that, in certain respects, are less detailed and/or less frequent than those of U.S. domestic reporting companies. For example, we are not required to issue quarterly reports, proxy statements that comply with the requirements applicable to U.S. domestic reporting companies, or individual executive compensation information that is as detailed 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 directors and executive officers are not required to report equity holdings under Section 16 of the Exchange Act and are not subject to the insider short-swing profit disclosure and recovery regime.

As a foreign private issuer, we are also exempt from the requirements of Regulation FD (Fair Disclosure) which, generally, are meant to ensure that select groups of investors are not privy to specific information about an issuer before other investors. However, we are still subject to the anti-fraud and anti-manipulation rules of the SEC, such as Rule 10b-5 under the Exchange Act. Since many of the disclosure obligations imposed on us as a foreign private issuer differ from those imposed on U.S. domestic reporting companies, you should not expect to receive the same information about us and at the same time as the information provided by U.S. domestic reporting companies.

As we are a "foreign private issuer" and follow certain home country corporate governance practices instead of otherwise applicable Nasdaq corporate governance requirements, our shareholders may not have the same protections afforded to shareholders of domestic U.S. issuers that are subject to all Nasdaq corporate governance requirements.

As a foreign private issuer, we have the option to, and we do, follow Israeli corporate governance practices rather than certain corporate governance requirements of Nasdaq, except to the extent that such laws would be contrary to U.S. securities laws, and provided that we disclose the requirements we are not following and describe the home country practices we follow instead. We have relied on this "foreign private issuer exemption" with respect to all the items listed under the heading "Item 16G. Corporate Governance," including with respect to shareholder approval requirements in respect of equity issuances and equity-based compensation plans, the requirement to have independent oversight on our director nominations process and to adopt a formal written charter or board resolution addressing the nominations process, the quorum requirement for meetings of our shareholders and the Nasdaq requirement to have a formal charter for the compensation committee. We may in the future elect to follow home country practices in Israel with regard to other matters. As a result, our shareholders may not have the same protections afforded to shareholders of companies that are subject to all Nasdaq corporate governance requirements. See *"Item 16G. Corporate Governance."*

We have never paid cash dividends on our ordinary shares and we do not anticipate paying any dividends in the foreseeable future. Consequently, any gains from an investment in our ordinary shares will likely depend on whether the price of our ordinary shares increases, which may not occur.

We have never declared or paid any cash dividends on our ordinary shares and do not intend to pay any cash dividends. Any agreements that we may enter into in the future may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our ordinary shares. In addition, Israeli law limits our ability to declare and pay dividends and may subject our dividends to Israeli withholding taxes. We anticipate that we will retain all of our future earnings for use in the development of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. Accordingly, investors must rely on sales of their ordinary shares after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

Risks Relating to Our Incorporation and Location in Israel

Our business could be adversely affected by political, economic and military instability in Israel and its region.

We are incorporated under Israeli law and our principal offices and manufacturing facilities are located in Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region may directly affect our business. Since the State of Israel was established in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors. Although Israel has entered into various agreements with Egypt, Jordan and the Palestinian Authority, there has been terrorist activity with varying levels of severity over the years. In October 7, 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 these terrorist organizations commenced in parallel to their continued rocket and terror attacks. Following the attack by Hamas on Israel's southern border, Hezbollah in Lebanon has also launched missile, rocket, and shooting attacks against Israeli military sites, troops, and Israeli towns in northern Israel. In response to these attacks, the Israeli army has carried out a number of targeted strikes on sites belonging to Hezbollah in southern Lebanon. It is possible that other terrorist organizations, including Palestinian military organizations in the West Bank, as well as other hostile countries, such as Iran, will join the hostilities. While we have not been materially impacted by Israel's current war to date, the intensity and duration of the current war is difficult to predict, as are such war's implications on our future business and operations. Further, in the event that our facilities (including our manufacturing facility in Beit Kama, which is located in southern Israel, approximately 20 miles east of the Gaza Strip) are damaged as a result of hostile action or hostilities otherwise disrupt the ongoing operation of our facilities or the airports and seaports on which we depend to import and export our supplies and products, our ability to manufacture and deliver products to customers could be materially adversely affected. Additionally, the operations of our Israeli suppliers and contractors may be disrupted as a result of hostile action or hostilities, in which event our ability to deliver products to customers may be materially adversely affected.

Our commercial insurance does not cover losses that may occur as a result of events associated with war. Losses resulting from acts of terrorism may be partially covered under certain circumstances. Although the Israeli government currently covers certain value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained or that it will sufficiently cover our potential damages. Any losses or damages incurred by us could have a material adverse effect on our business.

Further, in the past, the State of Israel and Israeli companies have been subjected to economic boycotts. Several countries, principally in the Middle East, restrict doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies if hostilities in Israel or political instability in the region continues or increases. These restrictions may limit materially our ability to obtain raw materials from these countries or sell our products to companies in these countries. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners, or significant downturn in the economic or financial condition of Israel, could adversely affect our operations and product development, cause our sales to decrease and adversely affect the share price of publicly traded companies having operations in Israel, such as us.

Prior to the Hamas attack in October 2023, the Israeli Government proposed a broad judicial reform in Israel. In response to the foregoing developments, individuals, organizations and institutions, both within and outside of Israel, voiced concerns that the proposed judicial reform, if adopted, may negatively impact the business environment in Israel including due to reluctance of foreign investors to invest or conduct business in Israel, as well as to increased currency fluctuations, downgrades in credit rating, increased interest rates, increased volatility in securities markets, and other changes in macroeconomic conditions. The risk of such negative developments has increased in light of the recent Hamas attacks and the war against Hamas declared by Israel, regardless of the proposed changes to the judicial system and the related debate. To the extent that any of these negative developments do occur, they may have an adverse effect on our business, financial condition, results of operations, growth prospects and market price of our shares, as well as on our ability to raise additional capital, if deemed necessary by our management and board of directors.

Our operations may be disrupted by the obligations of personnel to perform military service.

As of December 31, 2023, we had 347 employees based in Israel. Certain of our Israeli employees may be called upon to perform up to 36 days (and in some cases more) of annual military reserve duty until they reach the age of 40 (and in some cases, up to 45 or older) and, in emergency circumstances, could be called to active duty. In connection with the Israeli security cabinet's declaration of war against Hamas in October 2023 and possible hostilities with other organizations and jurisdictions, several hundred thousand Israeli military reservists were drafted to perform immediate military service. While we have not been impacted to date by any absences of our personnel, our operations could be disrupted by the absence of a significant number of our employees related to their, or their spouse's, military service or the absence for extended periods of one or more of our key employees for military service. Such disruption could materially adversely affect our business and results of operations. Additionally, the absence of a significant number of the employees of our Israeli suppliers and contractors related to military service or the absence for extended periods of one or more of their key employees for military service may disrupt their operations, in which event our ability to deliver products to customers may be materially adversely affected.

The tax benefits under Israel tax legislation that are or may be available to us require us to continue to meet various conditions and may be terminated or reduced in the future, which could increase our costs and taxes.

We obtained a tax ruling from the Israel Tax Authority according to which, among other things, our activity was qualified as an "industrial activity," as defined in the Israeli Law for the Encouragement of Capital Investments, 1959 (the "Investment Law"), and was eligible for tax benefits as a "Privileged Enterprise," which apply to the turnover attributed to such enterprise, for a period of up to ten years from the first year in which we generated taxable income. The tax benefits under the Privileged Enterprise status expired at the end of 2023. We have applied for a new tax ruling from the Israel Tax Authority according to which, if approved, among other things, our activity would be qualified as an "industrial activity," as defined in Investment Law, and we may be eligible for tax benefits according to the Investment Law, and our income from sales of our proprietary products (including royalties-based income) would be deemed "Preferred Technology Income" and "Preferred income" (within the meaning of the Investment Law). There can be no assurance that we will comply with the conditions required to remain eligible for benefits under the Investment Law in the future, including under the tax ruling (if obtained), or that we will be entitled to any additional benefits thereunder. If we do not fulfill these conditions in whole or in part, the benefits can be canceled and we may be required to refund the amount of the benefits, linked to the Israeli consumer price index, with interest.

In order to remain eligible for the tax benefits of under the Investment Law, we must continue to meet certain conditions stipulated in the Investment Law and its regulations, as amended, and must also comply with the conditions set forth in the tax ruling. These conditions may include, among other things, that the production, directly or through subcontractors, of all our products should be performed within certain regions of Israel. If we do not meet these requirements, the tax benefits would be reduced or canceled and we could be required to refund any tax benefits that we received in the past, in whole or in part, linked to the Israeli consumer price index, together with interest. Further, these tax benefits may be reduced or discontinued in the future. If these tax benefits are canceled, our Israeli taxable income would be subject to regular Israeli corporate tax rates. The standard corporate tax rate for Israeli companies is 23% since 2018. For more information about applicable Israeli tax regulations, see *"*Item 10. Additional Information — *E. Taxation — Israeli Tax Considerations and Government Programs."*

In the future, we may not be eligible to receive additional tax benefits under the Investment Law if we increase certain of our activities outside of Israel. Additionally, in the event of a distribution of a dividend from the abovementioned tax exempt income, in addition to withholding tax at a rate of 20% (or a reduced rate under an applicable double tax treaty), we will be subject to tax on the otherwise exempt income (grossed-up to reflect the pre-tax income that we would have had to earn in order to distribute the dividend) at the applicable corporate tax rate, which would have been applied had we not enjoyed the exemption. Similarly, in the event of our liquidation or a share buyback, we will be subject to tax on the grossed-up amount distributed or paid at the corporate tax rate which would have been applied had we not enjoyed the exemption. For more information about applicable Israeli tax regulations, see *"*Item 10. Additional Information — *E. Taxation — Israeli Tax Considerations and Government Programs."*

Tax matters, including changes in tax laws, adverse determinations by taxing authorities and imposition of new taxes could adversely affect our results of operations and financial condition. Furthermore, we may not be able to fully utilize our net operating loss carryforwards.

We are subject to the tax laws and regulations of the State of Israel and numerous other jurisdictions in which we do business. Many judgments are required in determining our provision for income taxes and other tax liabilities, and the applicable tax authorities may not agree with our tax positions. In addition, our tax liabilities are subject to other significant risks and uncertainties, including those arising from potential changes in laws and/or regulations in the State of Israel and the other countries in which we do business, the possibility of adverse determinations with respect to the application of existing laws, changes in our business or structure and changes in the valuation of our deferred tax assets and liabilities. As of December 31, 2023, we had net operating loss carryforwards ("NOLs") for tax purposes of approximately $26.9 million. If we are unable to fully utilize our NOLs to offset taxable income generated in the future, our future cash taxes could be materially and negatively impacted. For further detail regarding our NOLs, see Note 22 in our consolidated financial statements included in this Annual Report.

It may be difficult to enforce a U.S. judgment against us and our officers and directors in Israel or the United States, or to assert U.S. securities laws claims in Israel or serve process on our officers and directors.

We are incorporated in Israel. All of our directors and executive officers and the Israeli experts named in this Annual Report reside outside the United States. The majority of our assets and the assets of these persons are located outside the United States. Therefore, it may be difficult for an investor, or any other person or entity, to enforce a U.S. court judgment based upon the civil liability provisions of the U.S. federal securities laws against us or any of these persons in a U.S. or Israeli court, or to effect service of process upon these persons in the United States. Additionally, it may be difficult for an investor, or any other person or entity, to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws on the grounds that Israel is not the most appropriate forum in which to bring such a claim. Even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact by expert witnesses, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel addressing the matters described above.

Moreover, an Israeli court will not enforce a non-Israeli judgment if it was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases), if its enforcement is likely to prejudice the sovereignty or security of the State of Israel, if it was obtained by fraud or in the absence of due process, if it is at variance with another valid judgment that was given in the same matter between the same parties, or if a suit in the same matter between the same parties was pending before a court or tribunal in Israel at the time the foreign action was brought.

Your rights and responsibilities as our shareholder are 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 has a duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards the company and other shareholders and to refrain from abusing its power in the company, including, among other things, in voting at the general meeting of shareholders on certain matters, such as an amendment to the company's articles of association, an increase of the company's authorized share capital, a merger of the company 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 shareholder vote, or who has the power to appoint or prevent the appointment of an office holder in the company or has other powers towards the company, has a duty to act in fairness towards the company. However, Israeli law does not define the substance of this duty of fairness. See *"*Item 6. Directors, Senior Management and Employees *— Fiduciary Duties and Approval of Specified Related Party Transactions under Israeli Law — Duties of Shareholders."* There is limited case law available to assist us in understanding the nature of this duty or the implications of these provisions. 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.

Provisions of Israeli law and our articles of association may delay, prevent or make undesirable an acquisition of all or a significant portion of our shares or assets.

Certain provisions of Israeli law and our articles of association could have the effect of delaying or preventing a change in control and may make it more difficult for a third party to acquire us or for our shareholders to elect different individuals to our board of directors, even if doing so would be beneficial to our shareholders, and may limit the price that investors may be willing to pay in the future for our ordinary shares. For example, Israeli corporate law regulates mergers and requires that a tender offer be effected when more than a specified percentage of shares in a public company are purchased. Under our articles of association, a merger shall require the approval of two-thirds of the voting rights represented at a meeting of our shareholders and voting on the matter, in person or by proxy, and any amendment to such provision shall require the approval of 60% of the voting rights represented at a meeting of our shareholders and voting on the matter, in person or by proxy. Further, Israeli tax considerations may make potential transactions undesirable to us or to some of our shareholders, including such shareholders whose country of residence does not have a tax treaty with Israel granting tax relief to 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. Further, with respect to certain mergers, while Israeli tax law permits tax deferral, the deferral is contingent on certain restrictions on future transactions, including with respect to dispositions of shares received as consideration, for a period of two years from the date of the merger. Moreover, with respect to a certain share swap transaction, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no disposition of the shares has occurred. See Exhibit 2.1, *"*Description of Securities *—Acquisitions Under Israeli Law,"* incorporated herein by reference.

General Risks

The loss of one or more of our key employees could harm our business.

We depend on the continued service and performance of our key employees, including Amir London, our Chief Executive Officer, and our other senior management staff. We have entered into employment agreements with all of our senior management, including Mr. London, and other key employees. Either party, however, can terminate these agreements for any reason. The loss of key members of our executive management team could disrupt our operations, commercial and business development activities, or product development and have an adverse effect on our ability to meet our targets and grow our business.

Our ability to attract, recruit, retain and develop qualified employees is critical to our success and growth.

We compete in a market that involves rapidly changing technological and regulatory developments that require a wide-ranging set of expertise and intellectual capital. In order for us to successfully compete and grow, we must attract, recruit, retain and develop the necessary personnel who can provide the needed expertise across the entire spectrum of our intellectual capital needs. While we have a number of our key personnel who have substantial experience with our operations, we must also develop and exercise our personnel to provide succession plans capable of maintaining continuity in the midst of the inevitable unpredictability of human capital. However, the market for qualified personnel is competitive, and we may not succeed in recruiting additional experienced or professional personnel, retaining current personnel or effectively replacing current personnel who depart with qualified or effective successors. Many of the companies with which we compete for experienced personnel have greater resources than us.

Our effort to retain and develop personnel may also result in significant additional expenses, which could adversely affect our profitability. There can be no assurance that qualified employees will continue to be employed or that we will be able to attract and retain qualified personnel in the future. Failure to retain or attract qualified personnel could have a material adverse effect on our business, financial condition and results of operations.

We are subject to risks associated with doing business globally.

Our operations are subject to risks inherent to conducting business globally and under the laws, regulations and customs of various jurisdictions and geographies. These risks include fluctuations in currency exchange rates, changes in exchange controls, loss of business in government and public tenders that are held annually in many cases, nationalization, expropriation and other governmental actions, energy prices and higher prices and availability of raw materials, changes in taxation, importation limitations, export control restrictions, changes in or violations of applicable laws, including applicable anti-bribery and anti-corruption laws, such as the FCPA and the U.K. Bribery Act of 2010, pricing restrictions, economic and political instability, disputes between countries, personnel culture differences, diminished or insufficient protection of intellectual property, and disruption or destruction of operations in a significant geographic region regardless of cause, including war, terrorism, riot, civil insurrection or social unrest. For example, while our operations have not been materially impacted by Russia's invasion and ongoing military actions in Ukraine to date, we may not be able to continue to supply our products to our distributor in Russia, and even if we are able to continue the supply of product, there can be no assurance that our distributor in Russia may be able to pay us for such products given the actions by the Russian government to seize all international foreign currency payments. Failure to comply with, or material changes to, the laws and regulations that affect our global operations could have an adverse effect on our business, financial condition or results of operations.

As a result of our increased global presence, we face increasing challenges that could adversely impact our results of operations, reputation and business.

In light of our global presence, especially following our entry into new international markets and particularly in the MENA region, we face a number of challenges in certain jurisdictions that provide reduced legal protection, including poor protection of intellectual property, inadequate protection against crime (including bribery, corruption and fraud) and breaches of local laws or regulations, unstable governments and economies, governmental actions that may inhibit the flow of goods and currency, challenges relating to competition from companies that already have a local presence in such markets and difficulties in recruiting sufficient personnel with appropriate skills and experience.

Local business practices in jurisdictions in which we operate, and particularly in the MENA region, may be inconsistent with international regulatory requirements, such as anti-corruption and anti-bribery laws and regulations (including the FCPA and the U.K. Bribery Act of 2010) to which we are subject. Although we implement policies and procedures designed to ensure compliance with these laws, we cannot guarantee that none of our employees, contractors, service providers, partners, distributors and agents, will not violate our policies or applicable law. Any such violation could have an adverse effect on our business and reputation and may expose us to criminal or civil enforcement actions, including penalties and fines.

Developments in the economy may adversely impact our business.

Our operating and financial performance may be adversely affected by a variety of factors that influence the general economy in the United States, Europe, Israel, Russia, Latin America, Asia and other territories worldwide, including global and local economic slowdowns, challenges faced by banks and the health of markets for the sovereign debt. Many of our largest markets, including the United States, Latin America and states that are members of the Commonwealth of Independent States previously experienced dramatic declines in the housing market, high levels of unemployment and underemployment, and reduced earnings, or, in some cases, losses, for businesses across many industries, with reduced investments in growth.

A recessionary economic environment may adversely affect demand for our plasma-derived protein therapeutics. As a result of job losses, patients in the U.S. and other markets may lose medical insurance and be unable to purchase needed medical products or may be unable to pay their share of deductibles or co-payments. Hospitals may steer patients adversely affected by the economy to less costly therapies, resulting in a reduction in demand, or demand may shift to public health hospitals, which purchase our products at a lower government price. A recessionary economic environment may also lead to price pressure for reimbursement of new drugs, which may adversely affect the demand for our future plasma-derived protein therapeutics.

A breakdown in our information technology (IT) systems could result in a significant disruption to our business.

Our operations are highly dependent on our information technology (IT) systems. If we were to suffer a breakdown in our systems, storage, distribution or tracing, we could experience significant disruptions affecting all our areas of activity, including our manufacturing, research, accounting and billing processes and potentially cause disruptions to our manufacturing process for products currently in production. We may also suffer from partial loss of information and data due to such disruption.

Our business and operations would suffer in the event of computer system failures, cyber-attacks on our systems or deficiency in our cyber security measures.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication, electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. 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. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information and personal information, we could incur liability due to lost revenues resulting from the unauthorized use or theft of sensitive business information, remediation costs, and litigation risks including potential regulatory action by governmental authorities. In addition, any such disruption, security breach or other incident could delay the further development of our future product candidates due to theft or corruption of our proprietary data or other loss of information. Our business and operations could also be harmed by any reputational damage with customers, investors or third parties with whom we work, and our competitive position could be adversely impacted.

Tax legislation in the United States may impact our business.

Changes to the Internal Revenue Code, the issuance of administrative rulings or court decisions could impact our business. Tax legislation enacted in recent years made significant and wide-ranging changes to the U.S. Internal Revenue Code. Many aspects of such legislation that could affect our business remain subject to considerable uncertainty. Further, it is impossible to predict the occurrence or timing of any additional tax legislation or other changes in tax law that materially affect our business or investors.

Current and future accounting pronouncements and other financial reporting standards, especially but not only concerning revenue recognition, might negatively impact our financial results.

We regularly monitor our compliance with applicable financial reporting standards and review new pronouncements and drafts thereof that are relevant to us. As a result of new standards, changes to existing standards, including but not limited to IFRS 15 on revenue from contracts with customers that we adopted in 2018 and IFRS 16 on leases that we adopted in 2019 and changes in their interpretation, we might be required to change our accounting policies, particularly concerning revenue recognition, to alter our operational policies so that they reflect new or amended financial reporting standards, or to restate our published financial statements. Such changes might have an adverse effect on our reputation, business, financial position, and profit, or cause an adverse deviation from our revenue and operating profit target.

Increasing scrutiny of, and evolving expectations for, sustainability and environmental, social, and governance ("ESG") initiatives could increase our costs or otherwise adversely impact our business.

Public companies are facing increasing scrutiny related to ESG practices and disclosures from certain investors, capital providers, shareholder advocacy groups, other market participants and other stakeholder groups. Such increased scrutiny may result in increased costs, enhanced compliance or disclosure obligations, or other adverse impacts on our business, financial condition or results of operations. While we may at times engage in voluntary ESG initiatives, such initiatives may be costly and may not have the desired effect. If our ESG practices and reporting do not meet investor or other stakeholder expectations, which continue to evolve, we may be subject to investor or regulator engagement regarding such matters. In addition, new sustainability rules and regulations have been adopted and may continue to be introduced in various states and other jurisdictions. For example, the SEC has published proposed rules that would require companies to provide significantly expanded climate-related disclosures in their periodic reporting, which may require us to incur significant additional costs to comply and impose increased oversight obligations on our management and board of directors. Our failure to comply with any applicable rules or regulations could lead to penalties and adversely impact our reputation, access to capital and employee retention. Such ESG matters may also impact our third-party contract manufacturers and other third parties on which we rely, which may augment or cause additional impacts on our business, financial condition, or results of operations.

Item 4. Information on the Company

Corporate Information

We were incorporated under the laws of the State of Israel on December 13, 1990, under the name Kamada Ltd. In August 2005, we successfully completed an initial public offering on the TASE. In June 2013, we successfully completed an initial public offering in the United States on Nasdaq. The address of our principal executive office is 2 Holzman St., Science Park, P.O. Box 4081, Rehovot 7670402, Israel, and our telephone number is +972 8 9406472. Our website address is www.kamada.com. The reference to our website is intended to be an inactive textual reference and the information on, or accessible through, our website is not intended to be part of this Annual Report. The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements and other information regarding registrants like us that file electronically with the SEC. You can also inspect the Annual Report on that website.

We have irrevocably appointed Puglisi & Associates as our agent to receive service of process in any action against us in any United States federal or state court. The address of Puglisi & Associates is 850 Library Avenue, Suite 204, P.O. Box 885, Newark, Delaware 19715.

Capital Expenditures

For a discussion of our capital expenditures, see "Item 5. Operating and Financial Review and Prospects—*Liquidity and Capital Resources.*"

Business Overview

We are a commercial stage global biopharmaceutical company with a portfolio of marketed products indicated for rare and serious conditions and a leader in the specialty plasma-derived field focused on diseases of limited treatment alternatives. We are also advancing an innovative development pipeline targeting areas of significant unmet medical need. Our strategy is focused on driving profitable growth from our significant commercial catalysts as well as our manufacturing and development expertise in the plasma-derived and biopharmaceutical markets.

We operate in two segments: (i) the Proprietary Products segment, which includes our six FDA approved plasma-derived biopharmaceutical products - KEDRAB, CYTOGAM, VARIZIG, WINRHO SDF, HEPGAM B and GLASSIA, as well as KAMRAB, KAMRHO (D) and two types of equine-based anti-snake venom (ASV) products; all of which we market internationally in more than 30 countries. We manufacture our proprietary products at our cGMP compliant FDA-approved production facility located in Beit Kama, Israel, using our proprietary platform technology and know-how for the extraction and purification of proteins and IgGs from human plasma, as well as at third party contract manufacturing facilities; and (ii) the Distribution segment, in which we leverage our expertise and presence in the Israeli market by distributing, for use in Israel, more than 25 pharmaceutical products supplied by international manufacturers and in addition have eleven biosimilar products in our portfolio, which, subject to EMA and IMOH approvals, are expected to be launched in Israel through 2028.

As part of our Proprietary Products segment, we market KEDRAB, a human rabies immune globulin (HRIG), in the United States through a strategic distribution and supply agreement with Kedrion. Our 2023 revenues from sales of KEDRAB to Kedrion totaled $32.8 million as compared to $16.2 million and $11.9 million during 2022 and 2021, respectively. Such increase represents the increased demand for KEDRAB in the U.S. market in 2023. In December 2023, we entered into a binding memorandum of understanding with Kedrion for the amendment and extension of the distribution agreement between the parties, which represents the largest commercial agreement secured by us to date, according to which (among other things), within the first four years of the eight-year term, which began in January 2024, Kedrion will purchase minimum quantities of KEDRAB with aggregate revenues to us of approximately $180 million. KEDRAB's in-market sales in the United States grew significantly in 2023 as compared to 2022 and are currently expected to continue to grow through the eight-year term. The binding memorandum of understanding includes the potential expansion of KEDRAB distribution by Kedrion to other territories beyond the United States and the parties' agreement to collaborate to expand the distribution of Kedrion's products by us in Israel.

We sell CYTOGAM, a Cytomegalovirus Immune Globulin Intravenous (Human) (CMV-IGIV), indicated for prophylaxis of CMV disease associated with solid organ transplantation in the United States and Canada. Following FDA approval of the CYTOGAM technology transfer process obtained in May 2023, CYTOGAM manufactured at our Israeli facility has been available for commercial sale in the United States since October 2023. Total revenues from sales of CYTOGAM for the years ended December 31, 2023, and 2022 (the first full year during which we sold the product), were $17.2 million and $22.6 million, respectively. While our CYTOGAM sales decreased in 2023, available market information suggests that end-user utilization only marginally decreased between 2023 and 2022. We believe that the reduction in our sales of CYTOGAM in 2023 stemmed from inventory management by wholesalers, minimizing orders for short-dated inventory, with an expiry date of December 2023 or January 2024 (which inventory was acquired by us from Saol as part of the November 2021 acquisition; for details, see "Item 5. Operating and Financial Review and Prospects—Key Components of Our Results of Operations—*Business Combination*"), during the first nine months of the year until new batches of CYTOGAM manufactured at our Israeli facility became available commencing in October 2023. During the fourth quarter of 2023 and through January of 2024, monthly CYTOGAM sales increased as compared to average monthly sales during 2023, as did end user utilization. We believe that our clinical and medical affairs activities, including working with leading U.S-based transplantation experts on the collection and presentation of real-world data evaluating the advantages of CYTOGAM usage will continue to drive awareness of CYTOGAM, which in turn will support continued sales growth.

We believe that sales of KEDRAB and CYTOGAM which combined generated more than 50% of gross profitability in the year ended December 31, 2023, will continue to increase in the coming years and will be a major growth catalyst for the foreseeable future.

We sell VARIZIG, WINRHO SDF and HEPGAM B in the United States, Canada and several other international markets, mainly in South America and the Middle East and North Africa ("MENA") regions. Total revenues from sales of these products for the years ended December 31, 2023, and 2022 (the first full year during which we sold these products), was $26.7 million and $29.5 million, respectively. We believe that the decrease in sales of these products between the years is primarily associated with inventory management of our distributors as well as changes in supply schedules under certain tenders, and we expect sales of these products to grow in 2024 as compared to 2023.

We are entitled to royalty income on sales by Takeda of GLASSIA in the United States (as well as in Canada, Australia and New Zealand to the extent GLASSIA will be approved and sales will be generated in these other markets) at a rate of 12% on net sales through August 2025 and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually for each year from 2022 to 2040. During 2021, Takeda obtained a marketing authorization approval for GLASSIA from Health Canada, and it is expected to commence sales of GLASSIA in Canada during 2024, following which we will also be entitled to royalty income at the same rates from such sales. During 2023, we recognized total revenues for royalty income from Takeda of $16.1 million, as compared to $12.2 million during 2022 (which represented royalty income for the period between March and December of 2022). In 2022, we also recognized a $2.0 million one-time payment on account of the transfer, to Takeda, of the GLASSIA U.S. BLA. Based on current GLASSIA sales and forecasted future growth, we expect to receive royalties from Takeda in the range of $10 million to $20 million per year for 2024 to 2040 on GLASSIA sales. Historically, until mid-2021, we generated revenues on sales of GLASSIA, manufactured by us, to Takeda for further distribution in the United States.

We also market GLASSIA in other counties (mainly Russia, Argentina and Israel and in some of these markets under a different brand name) through local distributors. Total revenues derived from sales of GLASSIA in all other countries during 2023 was $7.4 million, as compared to $5.9 million and $7.6 million during 2022 and 2021, respectively. These ex-U.S. market sales of GLASSIA generated more than 40% gross margin in the year ended December 31, 2023. In May 2023, Swissmedic, the national authorization and supervisory authority for drugs and medical products in Switzerland, granted marketing authorization for GLASSIA for AATD in Switzerland. We have partnered with the IDEOGEN Group, a company focused on the commercialization of specialty medicines for rare diseases across Europe, for the commercialization of GLASSIA in Switzerland, and GLASSIA was commercially launched in Switzerland in December 2023, upon obtaining the required reimbursement coverage.

Our 2023 revenues from the sales of the remaining Proprietary products, including KAMRAB (a human rabies immune globulin (HRIG) sold by us outside the U.S. market) and KAMRHO (D) IM (for prophylaxis of hemolytic disease of newborns), as well as our anti-snake venoms sold to the IMoH, totaled $15.2 million, as compared to $13.9 million and $18.4 million during 2022 and 2021, respectively.

We own an FDA licensed plasma collection center that we acquired in March 2021 from the privately held B&PR based in Beaumont, Texas, which initially specialized in the collection of hyper-immune plasma used in the manufacture of KAMRHO (D). In 2023, we significantly expanded our hyper-immune plasma collection in this center by obtaining an FDA approval for the collection of hyper-immune plasma to be used in the manufacture of KAMRAB and KEDRAB, which is plasma that contains high levels of antibodies from donors who have been previously vaccinated by an active rabies vaccine, and started collections of such plasma during 2023. In March 2023, we entered into a lease agreement for a facility in Uvalde, Texas, and subsequently initiated construction activities to establish a new plasma collection center in that facility. We expect to commence plasma collection operations at this new center during 2024, following the completion of its construction and obtaining the required regulatory approvals. The new center is expected to collect normal source plasma to be sold for manufacturing by third parties, as well as hyper-immune specialty plasma required for manufacturing of our proprietary products. During early 2024, we plan to lease a subsequent facility and initiate construction activities to establish our third plasma collection center. We believe that the expansion of our plasma collection capabilities will allow us to better support our hyperimmune plasma needs as well as generate additional revenues through sales of collected normal source plasma.

Our Distribution segment is comprised of sales in Israel of pharmaceutical products manufactured by third parties. Sales generated by our Distribution segment during 2023 totaled $27.1 million, as compared to $26.7 million and $28.1 million during 2022 and 2021, respectively. The majority of the revenues generated in our Distribution segment are from plasma-derived products manufactured by European companies, and its sales represented approximately 76%, 75% and 84% of our Distribution segment revenues for the years ended December 31, 2023, 2022 and 2021, respectively. Over the past several years we continued to extend our Distribution segment products portfolio to non-plasma derived products, including entering into an agreement with Alvotech ehf. ("Alvotech") and two additional companies for the distribution in Israel of eleven different biosimilar products which, subject to EMA and subsequently IMOH approvals, are expected to be launched in Israel through 2028. We believe that sales generated by the launch of the biosimilar products portfolio will become a major growth catalyst. We currently estimate the potential aggregate peak revenues, achievable within several years of launch, generated by the distribution of all eleven biosimilar products to be in the range of approximately $30 million to $34 million annually.

In addition to our commercial operation, we invest in research and development of new product candidates. Our leading investigational product is Inhaled AAT for AATD, for which we are continuing to progress the InnovAATe clinical trial, a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial. We have additional product candidates in early development stage. For additional information regarding our research and development activities, see "— *Our Development Product Pipeline*".

We continue to focus on driving profitable growth through expanding our growth catalysts which include: investment in the commercialization and life cycle management of our commercial Proprietary products, led by KEDRAB and CYTOGAM sales in the U.S. market; continued growth of our Proprietary hyper-immune portfolio's revenues in existing and new geographic markets through registration and launch of the products in new territories; expanding sales of GLASSIA in ex-U.S. markets; generating royalties from GLASSIA sales by Takeda; expanding our plasma collection capabilities in support of our growing demand for hyper-immune plasma as well as sales of normal source plasma to other plasma-derived manufacturers; exploring strategic business development opportunities to identify a potential acquisition or in-licensing targeted product synergistic to our existing commercial activities that could be added to our proprietary products portfolio; continued increase of our Distribution segment revenues specifically through launching the eleven biosimilar products in Israel; and leveraging our FDA-approved IgG platform technology, manufacturing, research and development expertise to advance development and commercialization of additional product candidates, including our investigational Inhaled AAT product, and identify potential commercial partners for this product.

We currently expect to generate total revenues for the fiscal year 2024 in the range of $156 million to $160 million and adjusted EBITDA in the range of $27 million to $30 million. The projected 2024 revenue and adjusted EBITDA forecast represents double digit growth over fiscal year 2023. For details regarding the use of non-IFRS measures, see "Item 5. Operating and Financial Review and Prospectus—Non-IFRS Financial Measures."

Our Commercial Product Portfolio

Our commercial products portfolio includes our proprietary plasma-derived biopharmaceutical products in our Proprietary Products segment, which are marked and sold directly or through strategic partners and local distributers in the U.S., Canada, and additional markets worldwide, as well as licensed products, some of which are plasma-derived, which are marketed and sold by us in our Distribution segment in Israel.

Proprietary Products Segment

Our products in the Proprietary Products segment consist of plasma-derived IgGs and protein therapeutics derived from human plasma that are administered by injection or infusion. We also manufacture anti-snake venom products from equine based serum.

Our Proprietary Products segment sales totaled $115.5 million, $102.6 million and $75.5 million for the years ended December 31, 2023, 2022 and 2021, respectively. Revenues from sales of KEDRAB to Kedrion for further distribution in the U.S. market totaled $32.8 million, $16.2 million and $11.9 million for the years ended December 31, 2023, 2022 and 2021, respectively. For the years ended December 31, 2023, 2022 and 2021 (effective from November 22, 2021), combined revenues from sales of CYTOGAM, VARIZIG, WINRHO SDF and HEPAGAM B totaled $43.9 million, $52.1 million and $5.4 million, respectively. In 2023, we received a total of $16.1 million from Takeda of sales-based royalty income. In 2022, we recognized a total of $14.2 million as revenues from Takeda, of which $12.2 million of sales-based royalty income on account of GLASSIA sales by Takeda (for the period between March and December 2022) and a $2.0 million one-time payment on account of the transfer, to Takeda, of the GLASSIA U.S. BLA. Sales of GLASSIA to Takeda for further distribution in the U.S. were terminated during 2021; for the year ended December 31, 2021, our revenues from the sales of GLASSIA to Takeda totaled $26.2 million and we recognized also revenues of $5.0 million on account of a sales milestone associated with GLASSIA sales by Takeda. Sales of GLASSIA, other than to Takeda, for the years ended December 31, 2023, 2022 and 2021, totaled $7.4 million, $5.9 million and $7.6 million, respectively. Sales of our other Proprietary products accounted for the substantial balance of total revenues in the Proprietary Products segment for the years ended December 31, 2023, 2022 and 2021. Geographically, the substantial majority of our revenues from the Proprietary Products segment is generated from sales in the United States (64%, 64% and 66% for the years ended December 31, 2023, 2022 and 2021, respectively), and the remainder are primarily from sales in Latin America (11%, 11% and 12% for the years ended December 31, 2023, 2022 and 2021, respectively), Canada (10%, 10% and 0% for the years ended December 31, 2023, 2022 and 2021, respectively), Europe (6%, 5% and 8% for the years ended December 31, 2023, 2022 and 2021, respectively), Israel (4%, 5% and 10% for the years ended December 31, 2023, 2022 and 2021, respectively) and Asia (5%, 4% and 4% for the years ended December 31, 2023, 2022 and 2021, respectively).

The following tables lists our Proprietary Products:

Product	Indication	Active Ingredient
KAMRAB/ KEDRAB	Prophylaxis of rabies disease	Anti-rabies immunoglobulin (Human)
CYTOGAM	Prophylaxis of Cytomegalovirus (CMV) disease in kidney, lung, liver, pancreas, heart and heart/lung transplants	Cytomegalovirus Immune Globulin Intravenous (Human)
VARIZIG	Post exposure prophylaxis of Varicella in high risk individuals	Varicella Zoster Immunoglobulin (Human)
WINRHO SDF	Immune thrombocytopenic purpura (ITP) and suppression of rhesus isoimmunization (RH)	Rho(D) immunoglobulin (Human)
HEPAGAM B	Prevention of Hepatitis B recurrence liver transplants and post-exposure prophylaxis	Hepatitis B immunoglobulin (Human)
GLASSIA (or VENTIA/RESPIKAM in certain countries)	Intravenous AATD	Alpha-1 Antitrypsin (Human)
KAMRHO (D) IM	Prophylaxis of hemolytic disease of newborns	Rho(D) immunoglobulin (Human)
KAMRHO (D) IV	Treatment of immune thermobocytopunic purpura	Rho(D) immunoglobulin (Human)
Echis coloratus Antiserum, Vipera palaestinae Antiserum	Treatment of snake bites by the Vipera palaestinae and the Echis coloratus	Anti-snake venom

Propriety Products

KAMRAB/KEDRAB

KAMRAB is a hyper-immune plasma-derived therapeutic for prophylactic treatment against rabies infection that is administered to patients after exposure to an animal suspected of being infected with rabies. KAMRAB is manufactured at our manufacturing facility in Beit Kama, Israel from plasma that contains high levels of antibodies from donors that have been previously vaccinated by an active rabies vaccine. KAMRAB is administered by a one-time injection, and the precise dosage is a function of the patient's weight (20 IU/kg).

According to the WHO, rabies is estimated to cause 59,000 human deaths annually in over 150 countries and each year more than 29 million people worldwide receive a post-bite rabies vaccination, which is estimated to prevent hundreds of thousands of rabies deaths annually. The CDC recommends that PEP treatment for people who have never been vaccinated against rabies previously should always include administration of both Human Rabies Immuno Globulin (HRIG) and rabies vaccine. According to the CDC, the combination of HRIG and vaccine is recommended for both bite and non-bite exposures, regardless of the interval between exposure and initiation of treatment.

In July 2011, we signed a strategic distribution and supply agreement with Kedrion for the clinical development and marketing in the United States of KAMRAB, pursuant to which Kedrion agreed to bear all the costs required for the Phase 2/3 clinical trials. See "— Strategic Partnerships — *Kedrion (KAMRAB/KEDRAB)*." The results of a phase 2/3 study demonstrated that KAMRAB was non-inferior to the comparator HRIG product in achieving Rabies Virus Neutralizing Antibody (RVNA) levels of ≥0.5 IU/mL on day 14, when each was co-administered with a rabies vaccine. In addition, KAMRAB was found to be well-tolerated with a safety profile similar to that of the comparator HRIG product. Based on these results, in August 2017, we received FDA approval for the marketing of KAMRAB in the United States for PEP against rabies infection, and in April 2018 we, together with Kedrion, launched the product in the United States under the trademark KEDRAB.

In June 2021, the FDA approved a label update for KEDRAB, establishing the product's safety and effectiveness in children aged 0 to 17 years. The updates to the KEDRAB label were based on data from the KEDRAB U.S. post marketing pediatric study, the first and only clinical trial to establish pediatric safety and effectiveness of any HRIG in the United States. The KEDRAB U.S. pediatric trial was conducted at two sites, one in Arkansas and another in Rhode Island. The study included 30 pediatric patients (ages 0-17 years old), each of whom received KEDRAB as part of PEP treatment following exposure or suspected exposure to an animal suspected or confirmed to be rabid, and safety follow-up was conducted for up to 84 days. The primary objective of the study was to confirm the safety of KEDRAB in the pediatric population. Secondary objectives included the evaluation of antibody levels and the effectiveness of KEDRAB in the prevention of rabies disease when administered with a rabies vaccine according to the PEP recommended guidelines. No serious adverse events were observed during the study. No incidence of rabies disease or deaths were recorded throughout the 84-day study period. According to the CDC data, no children in the United States treated with post-exposure prophylaxis have been reported to have had rabies between 2018 and April 2021, which supports the use of KEDRAB in children.

Our revenues from sales of KEDRAB to Kedrion during 2023 totaled $32.8 million as compared to $16.2 million and $11.9 million during 2022 and 2021, respectively. Such increase represents the increased demand for KEDRAB in the U.S. market in 2023.

In December 2023, we entered into a binding memorandum of understanding with Kedrion for the amendment and extension of the distribution agreement between the parties, which represents the largest commercial agreement secured by us to date, according to which (among other things), within the first four years of the eight-year term, which began in January 2024, Kedrion will purchase minimum quantities of KEDRAB with aggregate revenues to us of approximately $180 million. KEDRAB's in-market sales in the United States grew significantly in 2023 as compared to 2022 and are currently expected to continue to grow through the eight-year term. The binding memorandum of understanding includes the potential expansion of KEDRAB distribution by Kedrion to other territories beyond the United States, and the parties' agreement to collaborate to expand the distribution of Kedrion's products by us in Israel.

CYTOGAM

CYTOGAM (Cytomegalovirus Immune Globulin Intravenous (Human)) (CMV-IGIV) is indicated for CMV disease associated with the transplantation of the kidney, lung, liver, pancreas and heart. CYTOGAM, approved by the FDA in 1998, is the sole FDA-approved immunoglobulin (IgG) product for this indication, and was acquired by us from Saol in November 2021.

CYTOGAM is administered within 72 hours after transplantation and then in weeks 2, 4, 6, 8, 12 and 16 after transplantation. The precise dosage is adjusted according to the patient's weight. CMV seroprevalence in the United States is estimated at 50-80% among adults. CMV is typically passed through direct personal contact. A seropositive status indicates exposure to the virus and development of antibodies against CMV. After initial infection, CMV establishes lifelong latency in the host. Immunocompetent individuals possess adequate immunity to protect them from infection and clinical symptoms, whereas immunocompromised patients, such as solid organ transplant patients, are vulnerable to both de novo primary and reactivation CMV infections. In the case of a solid organ transplant, CMV seronegative recipients (recipient negative (R-)) receiving CMV seropositive organs (donor positive (D+)) have the highest risk of CMV infection and disease. The occurrence of CMV infection in transplanted patients without prophylaxis in patients undergoing lung or heart-lung transplantation is 50%-75%, 9%-23% after heart transplantation, 22%-29% after liver transplantation, and 8%-32% after kidney transplantation. Investigational studies have shown that administration of CMV-IGIV is associated with neutralization of free CMV particles and immunomodulation that may attenuate and reduce the incidence of CMV disease post-transplant as part of a prophylactic regimen that includes concomitant anti-viral therapy.

Based on the Organ Procurement and Transplantation Network (OPTN), in the U.S., there were more than 46,630 solid organ transplant procedures performed during 2023. The OPTN also suggests that the number of transplants each year continues to grow and in each of the past 12 years, new annual records have been set in the number of deceased donors nationwide. Transplantation numbers have also grown as a result of increasing and more effective usage of organs from less traditional donors, including older individuals and people who have died of cardiorespiratory failure. Several available antivirals (ganciclovir and valganciclovir) are being used and are considered standards of care for the prevention of CMV infection in high-risk patients. As CMV infection in immunocompromised solid organ transplant patients can be severe and life-threatening, we believe that administration of CYTOGAM together with the available antivirals may provide additional protection in preventing CMV disease for certain high-risk transplant populations, such as lung and heart transplant. We believe there is an under-utilization of CYTOGAM as CMV prophylaxis in high-risk patients who undergo a solid organ transplant due to the lack of collection and presentation of new clinical and medical data and awareness regarding the benefits of combination of CYTOGAM and antiviral therapy, and that by addressing these deficits, increased utilization of CYTOGAM can be achieved.

In October 2023, the results of an investigator-initiated five-year retrospective study, conducted by Fernando Torres M.D., Clinical Chief, Division of Pulmonary and Critical Care at University of Texas Southwestern Medical Center, consisting of 325 lung-transplant patients, evaluating the real-world use of CYTOGAM in combination with anti-viral agents for the prevention of CMV disease in high-risk CMV mismatch lung transplant recipients (CMV seronegative patients receiving a lung from a seropositive donor), were presented at IDWeek 2023, in Boston, Massachusetts. Dr. Torres concluded his presentation by indicating that the use of a proactive multimodality CMV prophylaxis consisting of antivirals and immune augmentation with CMV immunoglobulin may improve outcomes among high-risk CMV mismatch lung transplant recipients.

CYTOGAM is registered and sold primarily in the United States and Canada. We are currently engaging key opinion leaders ("KOLs") in the U.S. in scientific knowledge exchange as well as to support further research of CYTOGAM, primarily in the form of investigator-initiated studies. In June 2023, we established a Scientific Advisory Board, consisting of eight U.S. based renowned thought leaders in the solid transplant world, which focuses on Kamada's U.S. clinical program for CYTOGAM including new opportunities and future research and development possibilities.

In May 2023, we received FDA approval to manufacture CYTOGAM at our facility in Beit Kama, Israel, and CYTOGAM manufactured at our Israeli facility has been available for commercial sale in the United States since October 2023. We had initially received FDA acknowledgment for the transfer of the ownership of the U.S. BLA for CYTOGAM in September 2022 and during December 2022, we submitted an application to the FDA, as a PAS, for approval to manufacture CYTOGAM at the Beit Kama facility. The FDA approval represents the successful conclusion of the technology transfer process of CYTOGAM from the previous manufacturer, CSL Behring. In July 2023, we also received the approval of Health Canada to manufacture CYTOGAM at our facility. We had initially obtained approval from Health Canada for the transfer of the DIN for CYTOGAM in June 2022 and we submitted a technology transfer application to Health Canada in January 2023, which was approved in July 2023.

Total revenues from sales of CYTOGAM for the years ended December 31, 2023 and 2022 (the first full year during which we sold the product), were $17.2 million and $22.6 million, respectively. While our CYTOGAM sales decreased in 2023, available market information suggests that end-user utilization only marginally decreased between 2023 and 2022. We believe that the reduction in our sales of CYTOGAM in 2023 stemmed from inventory management by wholesalers, minimizing orders for short-dated inventory, with an expiry date of December 2023 or January 2024 (which inventory was acquired by us from Saol as part of the November 2021 acquisition; for details, see "Item 5. Operating and Financial Review and Prospects—Key Components of Our Results of Operations—*Business Combination"*), during the first nine months of the year until new batches of CYTOGAM manufactured at our Israeli facility became available commencing in October 2023. During the fourth quarter of 2023 and through January of 2024, monthly CYTOGAM sales increased as compared to average monthly sales during 2023, as did end user utilization. We believe that our clinical and medical affairs activities, including working with leading U.S-based transplantation experts on the collection and presentation of real-world data evaluating the advantages of CYTOGAM usage, will continue to drive awareness of CYTOGAM, which in turn will support continued sales growth.

WINRHO SDF

WINRHO SDF is a Rho(D) Immune Globulin Intravenous (Human) product indicated for use in clinical situations requiring an increase in platelet count to prevent excessive hemorrhage in the treatment of non-splenectomies, for Rho(D)-positive children with chronic or acute ITP, adults with chronic ITP, and children and adults with ITP secondary to HIV infection. WINRHO SDF is also used for suppression of Rhesus (Rh) Isoimmunization during pregnancy and other obstetric conditions in non-sensitized, Rho(D)-negative women. WINRHO SDF, approved by the FDA in 1995, was acquired by us from Saol in November 2021.

Immune thrombocytopenic purpura (ITP) is a blood disorder characterized by a decrease in the number of platelets – the cells that help blood clot. Findings published during 2019 suggest that nearly 20,000 children and adults are newly diagnosed with ITP each year in the United States. Rho(D) immunoglobulin is an effective option for rapidly increasing platelet counts in patients with symptomatic ITP.

HDN is a blood disorder in a fetus or newborn infant. In some infants, it can be fatal. During pregnancy, Red Blood Cells (RBCs) from the unborn baby can cross into the mother's blood through the placenta. HDN occurs when the immune system of the mother sees a baby's RBCs as foreign. Antibodies then develop against the baby's RBCs. These antibodies attack the RBCs in the baby's blood and cause them to break down too early. Rho(D) immunoglobulin is administered to Rh-negative pregnant women as prophylactic therapy, to prevent the disease. The proportion of Rh-negative blood type differs from country to country and in the United States approximately 15% of people are Rh-negative.

In the U.S. market, WINRHO SDF is used almost solely as treatment of ITP. However due to an FDA black-box warning for Intravascular Hemolysis (IVH) issued in 2011, as well as the introduction of new ITP therapies, its sales in the U.S. market dropped significantly between 2011 to 2017 and have remained relatively flat since. The current use of WINRHO SDF in the U.S. market is for treatment of ITP in which it competes with other therapeutic agents, including TPO-RA agents, corticosteroids, IVIG and splenectomy.

We obtained FDA acknowledgment for the transfer of the ownership of the BLA for WINRHO SDF in September 2022. The ownership transfer of the DIN for WINRHO was approved by Health Canada in June 2022. The transfer of ownership of the DIN for WINRHO in other territories is still ongoing.

WINRHO SDF is currently manufactured by Emergent under a contract manufacturing agreement, which was assigned to us by Saol following the consummation of the acquisition. We expect to continue manufacturing the product with Emergent in the foreseeable future and are considering the initiation of a technology transfer for transitioning the manufacturing of WINRHO SDF to our manufacturing facility in Beit Kama, Israel. The initiation of such a technology transfer would be subject to executing a new revised manufacturing services agreement with Emergent covering operational aspects and the technology transfer related services and scope. We anticipate that once initiated, such a technology transfer may be completed within four to five years.

Our KAMRHO (D) is a comparable product to WINRHO SDF and approved for HDN. The two products are registered and distributed in different markets.

HEPAGAM B

HEPAGAM B is a hepatitis B Immune Globulin (Human) (HBIg) product indicated to both prevent hepatitis B virus (HBV) recurrence following liver transplantation in hepatitis B surface antigen positive (HBsAg- positive) patients and to provide post-exposure prophylaxis treatment. HEPAGAM B, which was approved by the FDA in 2006 for post-exposure prophylaxis and in 2007 as a prevention therapy, was acquired by us from Saol in November 2021.

Liver transplantation is the treatment of choice for patients with end-stage liver disease secondary to chronic hepatitis B. However, liver transplantation is complicated by the risk of recurrent hepatitis B virus infection, which significantly impairs graft and patient survival. Prevention of hepatitis B virus (HBV) reinfection includes use of antiviral therapy, with the addition of hepatitis B immune globulin. HBIG treatment is based upon the rationale that administered antibody will bind to and neutralize circulating virions, thereby preventing graft infection.

In the U.S. market, HEPAGAM B is mostly used for post-transplant prophylaxis in which it competes with Nabi-HB, a product of ADMA. Given the expected continued increase in liver transplants in the ex-U.S. countries, and our current registration and marketing activities in additional countries we believe product usage ex-U.S. may grow.

FDA acknowledgment of ownership transfer of the BLA of HEPAGAM B was received in September 2022. Health Canada approval for the DIN transfer was obtained in October 2022. We are in the process of submitting requests to transfer the registration of the product in other international countries as applicable**.**

HEPAGAM B is currently manufactured by Emergent under a contract manufacturing agreement which was assigned from Saol following the consummation of the acquisition. We expect to continue manufacturing the product with Emergent in the foreseeable future and are considering the initiation of a technology transfer for transitioning the manufacturing of HEPAGAM B to our manufacturing facility in Beit Kama, Israel. The initiation of such a technology transfer would be subject to executing a new, amended manufacturing services agreement with Emergent covering operational aspects and the technology transfer related services and scope. We anticipate that once initiated, such a technology transfer may be completed within four to five years.

VARIZIG

VARIZIG (Varicella Zoster Immune Globulin (Human)) is a product that contains antibodies specific for Varicella-zoster virus (VZV), and it is indicated for post-exposure prophylaxis of varicella (chickenpox) in high-risk patient groups, including immunocompromised children, newborns, and pregnant women. VARIZIG is intended to reduce the severity of chickenpox infections in these patients. The CDC recommends Varicella zoster immune globulin (human) (such as VARIZIG) for post-exposure prophylaxis of varicella for persons at high-risk for severe disease who lack evidence of immunity to varicella. VARIZIG, approved by the FDA in 2012, is the sole FDA-approved IgG product for this indication, and was acquired by us from Saol in November 2021.

Varicella-zoster virus (VZV) causes varicella (chicken pox) and herpes zoster (shingles). Varicella is a common childhood illness. Herpes zoster is caused by VZV reactivation. The incidence of herpes zoster increases with age or immunosuppression. Individuals at highest risk of developing severe or complicated varicella include immunocompromised people, preterm infants, and pregnant women. Varicella zoster immune globulin (human) (such as VARIZIG) is recommended by the CDC for post-exposure prophylaxis to prevent or attenuate varicella-zoster virus infection in high-risk individuals. VARIZIG may help these vulnerable patients to be defended against serious disease from varicella exposure. It has been demonstrated that post-exposure administration of VARIZIG was associated with low rates of varicella in high-risk patients.

In July 2022, we secured an $11.4 million agreement to supply VARIZIG to the PAHO, which also serves as Regional Office for the WHO, for further distribution in Latin America. The supply of the product under this agreement was made between the fourth quarter of 2022 and the first half of 2023.

FDA acknowledgment of ownership transfer of the BLA of VARIZIG was received in September 2022. Health Canada approval for the DIN transfer was obtained in June 2022.

VARIZIG is currently manufactured by Emergent under a contract manufacturing agreement which was assigned from Saol following the consummation of the acquisition. We expect to continue manufacturing the product with Emergent in the foreseeable future and are considering the initiation of a technology transfer for transitioning the manufacturing of VARIZIG to our manufacturing facility in Beit Kama, Israel. The initiation of such a technology transfer would be subject to executing a new, amended manufacturing services agreement with Emergent covering operation aspects and the technology transfer related services and scope. We anticipate that once initiated, such a technology transfer may be completed within four to five years.

In October 2022, we were awarded an extension of an existing tender from the Canadian Blood Services (CBS) for the supply of the four IgG products, CYTOGAM, HEPAGAM, VARIZIG and WINRHO SDF, for an additional three years, commencing on April 1, 2023, for an approximate total value of $22 million, securing the ongoing sales of those products in the Canadian market. During 2023 we supplied a total of $6.4 million under this contract. CBS manages the Canadian supply of blood products for all Canadian provinces and territories, excluding Quebec. We have an option to extend the agreement for up to two additional years. In addition, in Quebec, we also supply CYTOGAM, HEPAGAM, VARIZIG and WINRHO SDF under the agreement with Hema Quebec that was assigned to us from Saol.

GLASSIA

GLASSIA is an intravenous AAT product produced from fraction IV plasma that is indicated by the FDA for chronic augmentation and maintenance therapy in adults with emphysema due to congenital AATD. AAT is a naturally occurring protein found in a derivative of plasma known as fraction IV. AAT regulates the activity of certain white blood cells known as neutrophils and reduces cell inflammation. Patients with genetic AATD suffer from a chronic inflammatory state, lung tissue damage and a decrease in lung function. While GLASSIA does not cure AATD, it supplements the patient's insufficient physiological levels of AAT and is administered as a chronic treatment. As such, the patient must take GLASSIA indefinitely over the course of his or her life in order to maintain the benefits provided by it. GLASSIA is administered through a single weekly intravenous infusion.

In the United States and Europe, we believe that AATD is currently significantly under-diagnosed and under-treated. Based on information published by the Alpha-1 Foundation, there are approximately 100,000 people with AATD in the United States and about the same number in Europe, and we estimate, based on medical literature, that less than 10% of all potential cases of AATD are treated. We believe that the primary reasons for this significant gap in the U.S. and Europe are under diagnosis of patients suffering from AATD, the absence of insurance reimbursement in various countries, lengthy and complicated regulatory and reimbursement processes required to commence sales of AAT products in new markets. Similar reasons limit the diagnosis and usage of AATD treatment in other territories outside of the U.S. and Europe. We expect the number of patients treated for AATD to continue to increase going forward as awareness of AATD increases and given that a number of European countries have recently approved reimbursement for treatment of AATD, we believe that additional European countries will approve such reimbursement during the coming years. Based on a market analysis report published in 2023, the global AATD augmentation therapy market is expected to grow at a CAGR of 6.1% at least through 2032.

According to the Centers for Medicare and Medicaid Services, published payment allowance limits for Medicare part B, the average sale price, as of January 2024, of 10 mg of GLASSIA is $5.353, resulting in an annual cost of between $80,000 and $120,000 per each AATD patient, depending on the patient's body weight. In the United States, in some of the European countries and in Israel, Argentina and Russia we believe that the majority of the cost of treatment is covered by medical insurance programs.

GLASSIA was the first FDA-approved liquid AAT, which is ready for infusion and does not require reconstitution and mixing before infusion, as is required from most other competing products. Additionally, in June 2016, the FDA approved an expanded label of GLASSIA for self-infusion at home after appropriate training. GLASSIA has a number of advantages over other intravenous AAT products, including the reduction of the risk of contamination during the preparation and infection during the infusion, reduced potential for allergic reactions due to the absence of stabilizing agents, simple and easy use by the patient or nurse, and the possible reduction of the nurse's time during home visits, in the clinic or in the hospital and the ability of some of the patients to self- infuse at home.

The majority of sales of GLASSIA are in the United States, where it obtained FDA approval in July 2010 and sales commenced in September 2010. As part of the approval, the FDA requested that we conduct post-approval Phase 4 clinical trials, as is common in the pharmaceutical industry, aimed at collecting additional safety and efficacy data for GLASSIA. According to our agreement with Takeda (See "— Strategic Partnerships — Takeda (Glassia)."), the Phase 4 clinical trials are financed and managed by Takeda, provided that if the cost of such Phase 4 clinical trials exceeds a pre-defined amount, we will participate in financing such trial up to a certain amount by offsetting such amounts from future milestones, sales of GLASSIA or royalties from Takeda. The first Phase 4 safety study completed enrollment of a total of 30 subject in the U.S. and Canada during 2020 and its clinical study report was completed and was submitted to the FDA during 2022. The second Phase 4 efficacy study was initiated during 2016 and was terminated two years after initiation based on the DSMB's recommendation due to very low recruitment rates. During 2019, Takeda submitted a revised Phase 4 protocol to the FDA. Following several interactions with the FDA with respect to the Phase 4 efficacy study requirements, Takeda decided not to continue to pursue the study, and the current study status with the FDA is delayed.

We market GLASSIA in the United States through a strategic partnership with Takeda. During 2021, Takeda completed the technology transfer of GLASSIA manufacturing to its facility in Belgium and received the required FDA approval and initiated its own production of GLASSIA for the U.S. market. During the first quarter of 2022, Takeda began to pay us royalties on sales of GLASSIA manufactured by Takeda in the United States, at a rate of 12% on net sales through August 2025 and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually for each of the years from 2022 to 2040. During 2021, Takeda obtained a marketing authorization approval for GLASSIA from Health Canada, and in December 2023 Takeda announced that it has entered into a two year contract with the CBS for the supply of GLASSIA, which is expected to be initiated early 2024. Following the initiation of the supply to CBS we will be entitled to royalty income at the same rates from such sales. In 2023, we received a total of $16.1 million from Takeda of sales-based royalty income, as compared to $12.2 of sales-based royalty income from Takeda in 2022 (which represented royalty income for the period between March and December of 2022). In 2022, we also recognized a $2.0 million one-time payment on account of the transfer, to Takeda, of the GLASSIA U.S. BLA. Based on current GLASSIA sales and forecasted future growth, we expect to receive royalties on GLASSIA sales from Takeda in the range of $10 million to $20 million per year for 2024 to 2040. Historically, we generated revenues on sales of GLASSIA, manufactured by us, to Takeda for further distribution in the United States. In 2021, our revenues from the sale of GLASSIA to Takeda totaled $26.2 million and we also recognized revenues of $5.0 million on account of a sales milestone associated with GLASSIA sales by Takeda.

In May 2023, Swissmedic, the national authorization and supervisory authority for drugs and medical products in Switzerland, granted marketing authorization for GLASSIA for AATD in Switzerland. We have partnered with the IDEOGEN Group, a company focused on the commercialization of specialty medicines for rare diseases across Europe, for the commercialization of GLASSIA in Switzerland, and GLASSIA was commercially launched in Switzerland in December 2023, upon obtaining the required reimbursement coverage.

KAMRHO (D)

KAMRHO (D), similar to WINRHO SDF, is indicated for the prevention of Hemolytic Disease of the Newborn (HDN), which is a blood disorder in a fetus or newborn infant. In some infants, it can be fatal. During pregnancy, Red Blood Cells (RBCs) from the fetus can cross into the mother’s blood through the placenta. HDN occurs when the immune system of the mother sees a fetus’ RBCs as foreign. Antibodies then develop against the fetus' RBCs. These antibodies attack the RBCs in the fetus' or newborn's blood and cause them to break down too early. Rho(D) immunoglobulin is administered to Rh-negative pregnant women as prophylactic therapy, to prevent the disease. KAMRHO (D) is produced from hyper-immune plasma and is administered through intra-muscular injection (KAMRHO (D) IM).

SNAKE BITE ANTISERUM

Our snake bite antiserum products are used for the treatment of people who have been bitten by the most common Israeli Viper (*Vipera palaestinae)* and by the Israeli Echis *(Echis coloratus).* The venom of these snakes is poisonous and causes, among other symptoms, severe immediate pain with rapid swelling. These snake bites can lead to death if left untreated. Our snake bite antiserum products are produced from hyper-immune serum that has been derived from horses that were immunized against Israeli Viper and Israeli Echis venom. These products are the only treatment in the Israeli market for *Vipera palaestinae* and *Echis coloratus* snake bites.

We manufacture snake bite antiserums pursuant to an agreement with the IMOH entered into in March 2009, which was extended and amended in November 2022. The agreement with the IMOH was initially entered into following a tender that we won, and the extension of the agreement was under an exemption from a tender. We completed construction of the production facilities and laboratories for the product in accordance with the agreement and successfully passed the IMOH inspections. We began production of our snake bite antiserums in August 2011 and commenced sales to the IMOH in 2012. Under the agreement and subject to its terms, the IMOH has undertaken to purchase from us, and we have undertaken to supply the IMOH, a minimum quantity of snake bite antiserums each year during the term of the agreement. The agreement with the IMOH is currently in effect until September 2024. We plan to enter into discussions with the IMOH on the potential extension of the agreement prior to its expiration.

Plasma Collection

As part of our strategy of evolving into a fully integrated specialty plasma company, we established Kamada Plasma LLC, a wholly owned subsidiary, which operates our plasma collection activity in the United States. In March 2021, we completed the acquisition of the FDA licensed plasma collection center and certain related assets from the privately held B&PR based in Beaumont, Texas, which specializes in the collection of hyper-immune plasma used in the manufacture of Rho(D) immunoglobulin such as KAMRHO (D) and WINRHO SDF.

In 2023, we significantly expanded our hyper-immune plasma collection in this center through obtaining FDA approval for the collection of hyper-immune plasma to be used in the manufacture of KAMRAB and KEDRAB, which is plasma that contains high levels of antibodies from donors who have been previously vaccinated by an active rabies vaccine, and we started collections of such plasma during 2023. In March 2023, we entered into a lease agreement for a facility in Uvalde, Texas, and subsequently initiated construction activities to establish a new plasma collection center in that facility. We expect to commence plasma collection operations at this new center during 2024, following the completion of its construction and obtaining the required regulatory approvals. The new center is planned to collect normal source plasma to be sold for manufacturing by third parties, as well as hyper-immune specialty plasma required for manufacturing of our proprietary products. During 2024, we plan to lease a subsequent facility and initiate construction activities to establish our third plasma collection center. We believe that the expansion of our plasma collection capabilities will allow us to better support our plasma needs as well as generate additional revenues through sales of collected normal source plasma.

Distribution Segment

Our Distribution segment is comprised of marketing and sales in Israel of biopharmaceutical products manufactured by third parties. We engage third party pharmaceutical companies, register their products with the IMOH, import the products to Israel, market, sell and distribute them to local HMOs, hospitals and pharmacists. Sales generated by our Distribution segment during 2023 totaled $27.1 million, as compared to $26.7 million and $28.1 million during 2022 and 2021, respectively, and accounted for approximately 19%, 21% and 27% of our total revenues for the years ended December 31, 2023, 2022 and 2021, respectively. Our primary products in the Distribution segment include pharmaceuticals for critical care delivered by injection, infusion or inhalation. Currently, most of the revenues generated in our Distribution segment are from products produced from plasma or plasma-derivatives and are manufactured by European companies. IVIG is our primary product in the Distribution segment, comprising approximately 54%, 59% and 73% of total revenues in the Distribution segment for the years ended December 31, 2023, 2022 and 2021, respectively. The decrease in sales of IVIG during 2023 and 2022 as compared to previous years was as a result of supply shortages of our European manufacturers.

Over the past several years we continued to extend our Distribution segment products portfolio to non-plasma derived products and in December 2019, we entered into an agreement with Alvotech, a global biopharmaceutical company focused on biosimilars, to commercialize Alvotech's portfolio of six biosimilar product candidates in Israel, upon receipt of regulatory approval from the IMOH. During 2021 we added two additional products to the agreement, bringing the total number of products in the portfolio to eight. Alvotech's pipeline includes biosimilar product candidates aimed at treating autoimmunity, oncology and inflammatory conditions. Following receipt of the EMA marketing approval by Alvotech, and subject to subsequent approval by the IMOH, we expect to launch these products in Israel through 2028. In addition, in January 2021, we announced our entering into agreements with two undisclosed international pharmaceutical companies to commercialize three additional biosimilar product candidates in Israel. Subject to approval by the EMA and subsequently by the IMOH, the three products are expected to be launched in Israel through 2028. The two biopharmaceutical companies will maintain development, manufacturing and supply responsibilities for these three products. Based on the projected list price reduction due to the continued increase in competition as a result of the launch of additional biosimilar products and new competitors entering the biosimilar market, and anticipated market penetration potential, we currently estimate the potential aggregate peak revenues from the sale of all eleven products, achievable within several years of launch, to be in the range of approximately $30 million to $34 million annually.

The following table sets forth our primary products in the Distribution segment.

Product	Indication	Active Ingredient
Respiratory		
BRAMITOB	Management of chronic pulmonary infection due to pseudomonas aeruginosa in patients six years and older with cystic fibrosis	Tobramycin
FOSTER	Regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting beta2-agonist) is appropriate	Beclomethasone dipropionate, Formoterol fumarate
TRIMBOW	Maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) with Asthma Maintenance treatment of asthma	Beclomethasone dipropionate, Formoterol fumarate, Glycopyrronium as bromide
PROVOCHOLINE	Diagnosis of bronchial airway hyperactivity in subjects who do not have clinically apparent asthma	Methacholine Chloride
AEROBIKA	OPEP device	None
RUPAFIN	Symptomatic treatment of Allergic rhinitis and Urticaria	Rupatadine
RUPAFIN ORAL SOLUTION	Symptomatic treatment of allergic rhinitis in children aged 2 to 11 years and urticaria in children aged 2 to 11 years	Rupatadine
SINTREDIUS	Rheumatoid arthritis, systemic lupus erythematosus, mild-moderate juvenile dermatomyositis. Severe or debilitating allergic conditions, not treatable in a conventional manner such as: bronchial asthma in children, bronchial asthma in adults. Sarcoidosis in children and for maintenance therapy in adults. Acquired haemolytic anaemia.	Prednisolone as Sodium Phosphate
Immunoglobulins		
IVIG	Treatment of various immunodeficiency-related conditions	Gamma globulins (IgG) (human)
VARITECT	Preventive treatment after exposure to the virus that causes chicken pox and zoster herpes	Varicella zoster immunoglobulin (human)
ZUTECTRA	Prevention of hepatitis B virus (HBV) re-infection in HBV-DNA negative patients 6 months after liver transplantation for hepatitis B induced liver failure	Hepatitis B immunoglobulin (human)
HEPATECT CP	Prevent contraction of Hepatitis B by adults and children older than two years	Hepatitis B immunoglobulin (human)
MEGALOTECT CP	Contains antibodies that neutralize CMV viruses and prevent their spread in immunologically impaired patients	CMV immunoglobulin (human)
RUCONEST	Treatment of acute angioedema attacks in adults with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency	Conestat Alfa

Critical Care		
HEPARIN SODIUM INJECTION	Treatment of thrombo-embolic disorders such as deep vein thrombosis, acute arterial embolism or thrombosis, thrombophlebitis, pulmonary embolism, fat embolism. Prophylaxis of deep vein thrombosis and thromboembolic events	Heparin sodium
ALBUMIN and ALBUMIN	Maintains a proper level in the patient's blood plasma	Human serum Albumin
Coagulation Factors		
Factor VIII	Treatment of Hemophilia Type A diseases	Coagulation Factor VIII (human)
Factor IX	Treatment of Hemophilia Type B disease	Coagulation Factor IX (human)
COAGADEX	Treatment specifically for hereditary factor X deficiency	Coagulation factor X
Vaccinations		
IXIARO	Active immunization against Japanese encephalitis in adults, adolescents, children and infants aged 2 months and older	Japanese encephalitis purified inactivated vaccine
VIVOTIF	Immunization against disease caused by Salmonella Typhi	Typhoid vaccine live oral
Metabolic Disease		
PROCYSBI	Nephropathic cystinosis in adults and children 1 year of age and older	Cysteamine Biartrate
LAMZEDE	Treatment of alpha-mannosidosis	Velmanase alfa
Oncology		
ELIGARD	Management of advanced prostate cancer	Leuprolide acetate
BEVACIZUMAB KAMADA	A monoclonal antibody medication used to treat a number of types of cancers and a specific eye disease for cancer. It is given by slow injection into a vein (intravenous) and used for colon cancer, lung cancer, ovarian cancer, glioblastoma, and renal-cell carcinoma	Bevacizumab

Our Development Product Pipeline

Our research and development activities include conducting pre-clinical and clinical trials and other development activities for our Propriety pipeline products, improving existing products and processes, conducting development work at the request of regulatory authorities and strategic partners, as well as communicating with regulatory authorities regarding our commercial products and clinical and development programs. We incurred approximately$13.9 million, $13.2 million and $11.4 million in research and development expenses in the years ended December 31, 2023, 2022 and 2021, respectively.

We are in various stages of pre-clinical and clinical development of new product candidates for our Proprietary Products segment.

Inhaled Formulations of AAT for AATD

We are in the process of clinical development of an inhaled formulation of AAT administered through the use of a nebulizer. The nebulizer was developed by PARI. Inhaled AAT for AATD has been designated as an orphan drug for the treatment of AATD in the United States and Europe.

We have been able to leverage our expertise gained from the production of GLASSIA to develop a stable, high-purity Inhaled AAT product candidate for the treatment of AATD. Existing treatment for AATD require weekly intravenous infusions of AAT therapeutics. We believe that Inhaled AAT for AATD, if approved, will increase patient convenience and reduce or replace the need for patients to use intravenous infusions of AAT products, decreasing the need for clinic visits or nurse home visits, improving the patient's quality of life and reducing medical costs. If approved, Inhaled AAT for AATD is expected be the first AAT product that is not required to be delivered intravenously and instead is administered non-invasively by inhalation once daily.

The current standard care for AATD in the United States and in certain European countries, as well as in some additional international markets, is a weekly intravenous (IV) infusion of an AAT therapeutic. We estimate that only 2% of the AAT dose reaches the lung when administered intravenously. We have conducted a U.S. Phase 2 clinical study demonstrating that administration of an inhaled formulation of AAT through inhalation results in greater dispersion of AAT to the target lung tissue, including the lower lobes and lung periphery. Accordingly, the inhaled formulation of AAT requires a significantly lower therapeutic dose, estimated at approximately $1/8^{th}$ of the IV dose, and we believe it would be more effective in reducing inflammation of the lung tissue and inhibiting the uncontrolled neutrophil elastase that causes the breakdown of the lung tissue and the emphysema.

Because of the smaller amount of AAT dose used in Inhaled AAT for AATD (since it is applied directly to the site of action rather than administered systematically), we believe that this product, if approved, will enable us to treat significantly more patients from the same amount of plasma and production capacity and may be more cost effective for patients and payors and may increase our profitability.

We conducted a double-blind randomized placebo-controlled Phase 2/3 pivotal trial, under EMA guidance, which was completed at the end of 2013. A total of 168 patients participated in the trial in seven countries in Europe and Canada. Subjects in this trial were administered with a twice daily treatment of Inhaled AAT or equivalent dose of placebo for 50 consecutive weeks. The primary endpoint of the trial was the time from randomization to the first event-based exacerbation with a severity of moderate or severe. Other endpoints, which were secondary and tertiary, included additional exacerbation measures, lung function, and quality of life. The trial was 80% powered based on the number of exacerbation events collected in the study, in order to detect a difference between the two groups after 50 weeks. A 20% difference between the two groups was required to prove efficacy and was considered clinically meaningful, allowing the decision to prescribe the treatment. An open label extension of an additional 50 weeks on active drug was offered to study participants in most sites once they completed the initial 50-week period. Treatment in the open label extension of the trial was completed in November 2014.

This study did not meet its primary and secondary endpoints. However, lung function parameters, including Forced Expiratory Volume in One Second ("FEV1") % of Slow Vital Capacity ("SVC") and FEV1 % predicted, FEV1 (liters) which was collected to support safety endpoints, showed concordance of a potential treatment effect in the reduction of the inflammatory injury to the lung that is known to be associated with a reduced loss of respiratory function.

In accordance with guidance received following the meetings conducted with the European rapporteur and co-rapporteur, we performed several post hoc analyses. Results of the post hoc analyses indicated that after one year of daily inhalation of our Inhaled AAT, clinically and statistically significant improvements were seen in spirometric measures of lung function, particularly in bronchial airflow measurements FEV1 (L), FEV1% predicted and FEV1/SVC. These favorable results were even more evident when analyzing the overall treatment effect throughout the full year.

For lung function, overall effect for one year:

- FEV1 (L) rose significantly in AAT treated patients and decreased in placebo treated patients (+15ml for AAT vs. -27ml for placebo, a 42 ml difference, p=0.0268)
- There was a trend towards better FEV1% predicted (0.54% for AAT vs. -0.62% for placebo, a 1.16% difference, p=0.065)
- FEV1/SVC% rose significantly in AAT treated patients and decreased in placebo treated patients (0.62% for AAT vs. -0.87% for placebo, a 1.49% difference, p=0.0074)

For lung function change at week 50 vs. baseline:

- There was a trend towards reduced FEV1 (L)decline (-12ml for AAT vs. -62ml for placebo, a 50 ml difference, p=0.0956)
- There was a trend towards a reduced decline in FEV1% predicted (-0.1323% for AAT vs. -1.6205% for placebo, a 1.4882% difference, p=0.1032)
- FEV1/SVC% rose significantly in AAT treated patients and decreased in placebo treated patients (0.61% for AAT vs. -1.07% for placebo, a 1.68% difference, p=0.013)

During March 2014, we initiated a Phase 2 trial in the United States. The trial was completed in May 2016. This trial was intended to serve as a supplementary trial to the European Phase 2/3 trial and was designed to incorporate parameters required by the FDA. This Phase 2, double-blind, placebo-controlled study explored the Endothelial Lining Fluid ("ELF") and plasma concentration as well as safety of Inhaled AAT in AATD subjects. The subjects received one of two doses of Inhaled AAT or placebo. The study involved the daily inhalation of 80 mg or 160 mg of human AAT or placebo via the eFlow device for 12 weeks. Following the 12-week double blind period, the subjects were offered to participate in an additional 12 weeks open label period during which they receive only Inhaled AAT therapy. In December 2015, we completed the enrollment of patients in the study and in August 2016 we reported positive top-line results, according to which we met the primary endpoint.

AATD patients treated with our Inhaled AAT product in such U.S. Phase 2 clinical trial, demonstrated a significant increase in ELF AAT antigenic level compared to the placebo group (median increase 4551 nM, p-value<0.0005 (80 mg/day, n=12), and 13454 nM, p-value<0.002 (160mg/day, n=12)). These results are more than twice the increase of ELF antigenic AAT level (+2600 nM) observed in our previously completed intravenous AAT pivotal study (60mg/kg/week). Antigenic AAT represents the total amount of AAT in the lung, both active and inactive. The study results also showed that our Inhaled AAT is more efficient than IV to restore ELF AAT level within the lung. In addition, ELF Anti-Neutrophil Elastase inhibitory ("ANEC") level also increased significantly [median increase 2766 nM, p-value<0.0005 (80mg/day) and 3557 nM, p-value<0.004 (160 mg/day)]. The increase in ELF ANEC level was also more than twice that demonstrated in our previously completed IV AAT pivotal study. The ANEC level represents the active AAT that can counterbalance further damage by neutrophil elastase.

The updated data included in our poster presentation of May 2017 demonstrated that ELF-AAT, neutrophil elastase (NE)-AAT and ANEC complexes concentration significantly increased in subjects receiving the 80 mg and 160 mg doses, (median increase of 38.7 neutrophil migration (nM), p-value<0.0005 (80 mg/day, n=12), and median increase of 46.2 nM, p-value<0.002 (160 mg/day, n=10)). This is a specific measure of the anti-proteolytic effect in the ELF and represents the amount of NE that was broken down by AAT. The increase in levels of functional AAT was six times higher (160 mg per day) than is achievable with intravenous (IV) AAT. In addition, ELF NE decreased significantly. Also, the 80 mg data demonstrated a significant reduction in the percentage of neutrophils. Finally, aerosolized M-specific AAT was detected in the plasma of all subjects receiving Inhaled AAT, consistent with what was seen in the Phase 2/3 clinical trial of our Inhaled AAT conducted in the EU.

We filed the MAA for our Inhaled AAT for AATD during the first quarter of 2016 and in June 2017 we withdrew the MAA, as following extensive discussions with the EMA we concluded that the EMA did not view the data submitted as sufficient, in terms of safety and efficacy, for approval of the MAA, and that the supplementary data needed for approval required an additional clinical trial. While the post-hoc data indicated a statistically significant and clinically meaningful improvement in lung function, the EMA was of the opinion that an overall positive conclusion on the effect of Inhaled AAT for AATD could not be reached based on that post-hoc analysis, and that the treatment of AATD patients with our Inhaled AAT product should be further evaluated in the clinic in order to obtain comprehensive long-term efficacy and safety data. The EMA was of the opinion that the study failed to show sufficient beneficial effects in the population studied. In addition, there were concerns about the tolerability and safety profile of the AAT, mainly in patients with severe lung disease. Lastly, the EMA raised concerns about the high rate of patients with antibodies (ADA) responding to AAT, which might reduce its effects or make patients more prone to allergic reactions, despite evidence that none of the patients with such ADA response had allergic reaction nor a lower level of AAT in the serum. When presented with the European Phase 2/3 study data, the FDA expressed concerns and questions in connection with the safety and efficacy of Inhaled AAT for the treatment of AATD and the risk/benefit balance to patients based on that data and product characteristics.

Following several discussions with the FDA and EMA, through which additional data and information were provided and we addressed both agencies' guidance with respect to our proposed subsequent Phase 3 pivotal study protocol, we received positive scientific advice from the Committee of Medicinal Products for Human Use ("CHMP") of the EMA related to the development plan for our proposed pivotal Phase 3 pivotal study for Inhaled AAT for AATD, and in April 2019, we received a letter from the FDA stating that we had satisfactorily addressed their concerns and questions with respect to the proposed Phase 3 clinical trial.

During December 2019, we initiated our Phase 3 InnovAATe trial, under an FDA IND (Investigational New Drug Application) and a European CTA (Clinical Trial Application) and announced the first-patient-in. InnovAATe is a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial designed to assess the efficacy and safety of Inhaled AAT in patients with AATD and moderate lung disease. Up to 220 patients will be randomized 1:1 to receive either Inhaled AAT at a dose of 80mg once daily, or placebo, over two years of treatment. The primary endpoint of the InnovAATe trial is lung function measured by FEV1. Secondary endpoints include lung density changes as measured by CT densitometry, as well as other parameters of disease severity, such as additional pulmonary functions, exacerbation rate and six-minute walk test. The safety profile will be monitored continuously by a Data Monitoring Committee with predefined rules to be applied after the first 60 subjects have completed six months of treatment. The study is led by Jan Stolk, M.D., Department of Pulmonology, Member of European Reference Network LUNG, Leiden University Medical Center, the Netherlands.

During 2020, 2021 and until the beginning of 2022, enrolment in the pivotal Phase 3 InnovAATe clinical trial was negatively affected by the impact of COVID-19 pandemic on healthcare systems. During the second half of 2022 and 2023, following the moderation of the pandemic and gradual recovery of health systems in Europe, the study was expanded across Europe and enrollment accelerated. Additional clinical sites are planned to be opened in 2024. As of March 1, 2024, 78 patients had enrolled in the study, 19 of whom had completed the two-year study treatment period at the initial trial site in Leiden, the Netherlands. To date, only five patients discontinued treatment prematurely, only one due to safety events related to the exposure to the study drug, and no drug-related serious adverse events were reported. Additionally, as part of routine and planned monitoring processes, and for the sixth time since study initiation, the independent DSMB recently recommended that the trial continue without modification. Moreover, based on a safety assessment performed for the first 42 patients (which included treatment duration per patient ranging between 6 and 24 months), the DSMB advised that a safety assessment for 60 patients (completing six months of treatment) be waived and that due to the favorable safety of the study to date, there is no need for further dedicated safety assessment beyond the standard DSMB bi-annual meetings.

During the second quarter of 2023, we received scientific advice from the EMA CHMP regarding the ongoing pivotal InnovAATe trial for Inhaled AAT that reconfirms the overall design of the study and acknowledges the statistically and clinically meaningful improvement in lung function (FEV1) demonstrated in our previously completed Phase 2/3 European study, which served as the basis for the design and the selection of the primary endpoint of our current Phase 3 study.

In January 2024, we conducted a meeting with the FDA regarding the progress of the ongoing InnovAATe study, during which the FDA reconfirmed the overall design of the study and endorsed the DSMB unblinded positive safety assessment of 42 patients, accepting the DSMB's recommendation to waive the need for an additional safety assessment point of 60 patients with at least six months of treatment. During the meeting, the FDA also accepted our plan to conduct an open label extension study, which is expected to be initiated mid-2024, and expressed willingness to potentially accept a $P<0.1$ alpha level in evaluating InnovAATe for meeting the efficacy primary endpoint for registration, which may allow for the acceleration of the program. As a result, we plan to present a revised statistical analysis plan (SAP) and study protocol for the InnovAATe study and to seek the FDA's feedback by mid-2024.

Prior to the initiation of the pivotal Phase 3 InnovAATe clinical trial we completed a Human Factor Study (HFS) to support the combination product, consisting of our Inhaled AAT and the investigational eFlow nebulizer system of PARI Pharma GmbH. Based on feedback received from the FDA, we conducted a subsequent HFS to support an improved use regimen of the product, which was implemented in the InnovAATe study.

In addition to the pivotal study and based on feedback received from the FDA regarding ADAs to Inhaled AAT, we intend to concurrently conduct a sub-study in North America in which approximately 30 patients will be evaluated for the effect of ADA on AAT levels in plasma with Inhaled AAT and IV AAT treatments. The study design and protocol were acceptable by the FDA, and its initiation is planned for 2025.

We continue to evaluate partnering opportunities for the future commercialization of the Inhaled AAT product in the U.S. and Europe.

Anti-SARS-CoV-2 IgG Product as a Potential Treatment for COVID-19

In response to the COVID-19 outbreak, in early 2020 we initiated the development of a human plasma-derived Anti-SARS-CoV-2 polyclonal immunoglobulin (IgG) product using our proprietary plasma-derived IgG platform technology as a potential treatment for COVID-19. The development of our investigational Anti-SARS-CoV-2 IgG product was done using COVID-19 convalescent plasma, with full cooperation with IMOH, and included conducting a Phase 1/2 open-label, single-arm, multi-center clinical trial in Israel, which was followed by the supply, during 2021, of this investigational product to the IMOH for the treatment of approximately 500 COVID-19 patients in Israel.

Given the increased vaccination rate of the population, the approvals of monoclonal antibodies for COVID-19 and the subsequent moderation of the pandemic, we discontinued this development program.

Recombinant AAT

During 2020 we initiated the development of a recombinant human Alpha 1 Antitrypsin ("rhAAT") product, focusing on therapeutic indications which would potentially leverage the immune-modulatory mechanism of action of the protein. As part of this project we developed analytical tools that support the selection of the appropriate cell lines and characterization of the product. We engaged Cellca, a CDMO located in Germany, part of Sartorius Stedim BioTech Group, to pursue the cell line development of the rhAAT in Chinese hamster ovary cells with the goal of developing a product of high productivity and robust quality. During 2022 and 2023, we studied the clones previously selected using in vitro and in vivo models, elucidating the immuno-modulatory properties of the protein.

We currently do not plan to continue the development of this product independently and are looking to attract a strategic partner to collaborate in the further development of this product.

Other early-stage development programs

During 2023, we advanced three early-stage development programs of plasma derived product candidates. These programs include: (i) a human plasma-based eye drops for potential treatment of several ocular conditions. The product is currently under CMC development and pre-clinical evaluation; (ii) an automated portable small scale system for extraction and purification of hyperimmune IgG from convalescent plasma, at the hospital/blood bank setting, for immediate response to a variety of unmet medical needs, including pandemic outbreaks, as well as possible treatment of currently neglected or untreated viral diseases. The initial design of the system was completed and we are currently in the process of seeking regulatory guidance for the advancement of this product development; and (iii) a hyperimmune anti-tuberculosis IgG as a potential complementary treatment to existing standard of care. The program is developed in collaboration with the Clinical Microbiology and Immunology department of the Medicine-Sackler Faculty of Tel Aviv University and is partially funded by the Israel Innovation Authority. In 2023, the anti-tuberculosis IgG was developed and produced in small R&D scale and assessed *in-vitro*, and we plan to test the product *in-vivo* during 2024.

We plan to advance these programs until completion of proof-of-concept, at which point we plan to evaluate continued internal development, partnering or out-licensing.

Strategic Partnerships

We currently have strategic partnerships with a number of different companies regarding the distribution and/or development of our products portfolio. Certain strategic partnerships relating to our Proprietary Products segment are discussed below.

Kedrion (KEDRAB)

On July 18, 2011, we signed an agreement with Kedrion, a biopharmaceutical company that collects and fractionates blood plasma to produce and distribute worldwide plasma-derived therapies for use in treating and preventing rare and debilitating conditions such as coagulation and neurological disorders and primary and secondary immunodeficiencies. The agreement provided for exclusive cooperation on completing the clinical development, and marketing and distribution of our anti-rabies immunoglobulin, KAMRAB, in the United States under the brand name KEDRAB. Pursuant to the agreement, Kedrion bore all the costs of the Phase 2/3 clinical trials in the United States of our product. Pursuant to the agreement, costs related to any Phase 4 clinical trials and the FDA Prescription Drug User fee required for all new approved drugs were divided equally between us and Kedrion. In October 2016, we entered into an addendum to the agreement with respect to the performance of a safety clinical trial for the treatment of pediatric patients in the United States, pursuant to which we and Kedrion agreed to equally share the cost of such trial. The agreement was further supplemented in October 2018 and June 2019, with regard to the determination of purchase price and payment terms under the agreement.

The agreement provides exclusive rights to Kedrion to market and sell KEDRAB in the United States. We retain intellectual property rights to KEDRAB. Kedrion is obligated to purchase a minimum amount of KEDRAB per year during the term of the agreement.

In April 2018, following the receipt of an FDA marketing authorization, KEDRAB was launched in the United States. For more information about the product see above "Item 4. Information on the Company — *Proprietary Products Segment* — Our Commercial Product Portfolio — *Propriety Products — KAMRAB/KEDRAB*".

The term of the original agreement was for six years commencing on the date by which KEDRAB U.S. launch was feasible (i.e., until March 2024), and Kedrion had an option to extend the term by two additional years, until March 2026, which it exercised in July 2023. In addition to customary termination provisions (including the right of either party to terminate the agreement if the other party fails to perform or violates any provision of the agreement in any material respect and the failure continues unremedied for a defined period), Kedrion has the right to terminate the agreement, upon prior written notice, (i) for any reason after receipt of FDA approval, (ii) in the event that the FDA BLA is suspended or revoked and cannot be reinstated within a certain period of time, or (iii) a major regulatory change occurs that materially and adversely increases the clinical trial costs. We have the right to terminate the agreement in the event that (i) a major regulatory change occurs that materially and adversely increases the manufacturing costs of KEDRAB, (ii) a major regulatory change occurs that poses considerable difficulties on submission of an application for FDA approval or (iii) clinical trials are not initiated within a certain time after either receipt by Kedrion of enough product or FDA approval to begin clinical trials. Upon termination or expiration of the agreement, Kedrion's exclusive rights to market and sell KEDRAB in the U.S. market will be canceled, at which point we may elect to market and sell the product in the U.S. market on our own or otherwise engage a different distributor.

In December 2023, we entered into a binding memorandum of understanding with Kedrion for the amendment and extension of the distribution agreement between the parties, which represents the largest commercial agreement secured by us to date, according to which (among other things), the distribution agreement was extended until December 31, 2031, and Kedrion shall have the right to extend the agreement, by written notice no later than December 31, 2030, for an additional two years, until December 31, 2033. Under the terms of the binding memorandum of understanding, during fiscal years 2024 through 2027, Kedrion will purchase in total minimum quantities of KEDRAB, with currently anticipated aggregate revenues to us of approximately $180 million for such four-year period. KEDRAB's in-market sales in the United States grew significantly in 2023 as compared to 2022 and are currently expected to continue to grow through the eight-year term. The binding memorandum of understanding includes the potential expansion of KEDRAB distribution by Kedrion to other territories beyond the U.S., and the parties' agreement to collaborate to expand the distribution of Kedrion's products by us in Israel. The binding memorandum of understanding shall remain in effect until the earlier of the parties entering into detailed agreements with respect to the subject matter thereof or the termination of the distribution agreement.

Takeda (GLASSIA)

We have a partnership arrangement with Takeda that includes three main agreements: (1) an exclusive manufacturing, supply and distribution agreement, pursuant to which through 2021 we manufactured GLASSIA for sale to Takeda for further distribution in the United States, Canada, Australia and New Zealand (through the end of 2023 GLASSIA was distributed by Takeda only in the United States); (2) a technology license agreement, which grants Takeda licenses to use our knowledge and patents to produce, develop and sell GLASSIA; and (3) a fraction IV-I paste supply agreement, pursuant to which Takeda supplies us with fraction IV plasma, a plasma derivative, produced by Takeda, as discussed under "— Manufacturing and Supply — Raw Materials — *Plasma derived Fraction IV paste for GLASSIA manufacturing."* Other than with respect to plasma-derived AAT administrated by IV, we retain all rights, including distribution rights of GLASSIA in all territories other than the ones mentioned above as well as distribution rights to any other form of AAT administration, including Inhaled AAT.

The agreements were originally executed with Baxter Healthcare Corporation ("Baxter") in August 2010. During 2015, Baxter assigned all its rights under the agreements to Baxalta US Inc. ("Baxalta"), an independent public company which spun-off from Baxter. In 2016, Shire plc. ("Shire") completed the acquisition of Baxalta, and as a result, all of Baxalta's rights under the agreements were assigned to Shire. In January 2019, Takeda completed its acquisition of Shire, and all rights under the agreement transferred to Takeda.

Exclusive Manufacturing, Supply and Distribution Agreement

Pursuant to the exclusive manufacturing, supply and distribution agreement, as amended from time to time, Takeda was obligated to purchase a minimum amount of GLASSIA per year until the end of 2021. Under the agreement, Takeda is also obligated to fund required Phase 4 clinical trials related to GLASSIA up to a specified amount, and if the costs of such clinical trials are in excess of this amount, we agreed to fund a portion of the additional costs. We also undertook to reimburse Takeda for its GLASSIA marketing efforts up to a limited amount during the years 2017-2020.

In November 2021, pursuant to the technology license agreement described below, Takeda completed the technology transfer of GLASSIA manufacturing, and initiated its own production of GLASSIA for the U.S. market. Accordingly, we completed the supply of GLASSIA to Takeda and, and through the end of 2023 we remained an approved supplier of the product. We do not anticipate continuing to manufacture and supply GLASSIA to Takeda under the exclusive manufacturing, supply and distribution agreement.

Technology License Agreement

The technology license agreement provides an exclusive license to Takeda, with the right to sub-license to certain manufacturing parties, of our intellectual property and know-how regarding the manufacture and additional development of GLASSIA for use in Takeda's production and sale of GLASSIA in the United States, Canada, Australia and New Zealand. Pursuant to the technology license agreement, we were entitled to receive payments for the achievement of certain development-based milestones related to the transfer of technology to Takeda and sales-based milestones. To date, we have received the total aggregate milestone payments under the agreement ($20 million).

Pursuant to the technology license agreement, following the initiation of GLASSIA manufacturing by Takeda, Takeda is required to pay us royalties at a rate of 12% on net sales through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually, for each of the years from 2022 to 2040. During the first quarter of 2022, Takeda began to pay us royalties on sales of GLASSIA manufactured by them in the United States. During 2021 Takeda received an approval from Health Canada for the marketing and distribution of GLASSIA in Canada, and it is expected to commence sales of GLASSIA in Canada in early 2024, following which we will be entitled to royalty income at the same rates from such sales. For the year ended December 31, 2023, and the period between March and December 2022, we accounted for $16.1 million and $12.2 million, respectively, of sales-based royalty income from Takeda.

Pursuant to an amendment to the license agreement entered into in March 2021, upon completion of the transition of GLASSIA manufacturing to Takeda, which was completed in November 2021, we transferred to Takeda the GLASSIA U.S. BLA, in consideration of an additional $2.0 million payment, which was paid to us in March 2022, following the FDA's acknowledgment of the BLA transfer.

Pursuant to the technology license agreement, the intellectual property rights for any improvements on the manufacturing process or formulations belong to the party that develops the improvements, with each party agreeing to cross-license the developed improvements to the other party. We retain an option to license any intellectual property developed by Takeda under the agreement that is not considered an improvement on the licensed technology. Additionally, Takeda owns any intellectual property it develops using the licensed technology for new indications for the intravenous AAT product, for which we retain an option to license at rates to be negotiated. Any technology related to new indications for the intravenous AAT product developed by us during the royalty payments period will be part of the licensed technology covered by the technology license agreement.

The technology license agreement expires in 2040. Either party may terminate the agreement, in whole or solely with respect to one or more countries covered by the distribution agreement, pursuant to customary termination provisions. Takeda also has the right to terminate the agreement, upon prior written notice, in the event that: (i) our manufacturing process technology for GLASSIA is determined to materially infringe upon a third party's intellectual property rights, and we have not obtained a license to such third party's intellectual property or provided an alternative non-infringing manufacturing process; (ii) there are certain decreases in GLASSIA sales in the United States unless such decreases are due to transfers to Inhaled AAT for AATD; or (iii) the regulatory approval process in the United States has been withdrawn or rejected as a result of our inaction or lack of diligent effort, provided such withdrawal or rejection was not primarily caused by the breach by Takeda of its obligations. We have the right to terminate the agreement, upon prior written notice: (i) if Takeda contests or infringes upon our intellectual property; (ii) if regulatory approval in one or more countries covered by the technology license agreement is withdrawn or rejected and not reversed, provided it was not primarily caused by the breach by us of our obligations; or (iii) in the event that GLASSIA produced by Takeda, other than as a result of our manufacturing process technology, is determined to materially infringe upon a third party's intellectual property rights, provided that the termination right is limited only to the country in which such judgment is binding. Following any termination, other than expiration of the agreement, all licensed rights will revert to us.

Upon expiration of the agreement, Takeda will be entitled to a non-exclusive, perpetual, royalty free license.

PARI

On November 16, 2006, we entered into a license agreement with PARI (the "Original PARI Agreement") regarding the clinical development of an inhaled formulation of AAT, including Inhaled AAT for AATD, using PARI's "eFlow" nebulizer. Under the Original PARI Agreement, we received an exclusive worldwide license, subject to certain preexisting rights, including the right to grant sub-licenses, to use the "eFlow" nebulizer, including the associated technology and intellectual property, for the clinical development, registration, and commercialization of inhaled formulations of AAT to treat AATD and respiratory deterioration, and to commercialize the device for use with such inhaled formulations. The agreement also provided for PARI's cooperation with us during the pre-clinical phase and other clinical phases of development of Inhaled AAT, where each of the parties was responsible for developing and adapting its own product and bore the costs involved.

Pursuant to the Original PARI Agreement, we agreed to pay PARI royalties from future sales of Inhaled AAT, after certain deductions, at the rates specified in the agreement. We have agreed to pay PARI tiered royalties ranging from the low single digits up to the high single digits based on the annual net sales of inhaled formulations of AAT for the applicable indications. The royalties will be paid for each country separately, until the later of (1) the expiration of the last of certain specified patents covering the "eFlow" nebulizer, or (2) 15 years following the first commercial sale of an inhaled formulation of AAT in that country (the "PARI Royalty Period"). During the PARI Royalty Period, PARI is obligated to pay us specified percentages of its annual sales of the "eFlow" nebulizer for use with Inhaled AAT above a certain threshold defined in the agreement and after certain deductions.

On February 21, 2008, we entered into an addendum to the Original PARI Agreement (together with the Original PARI Agreement, the "PARI Agreement"), which extended the exclusive global license granted to us to use the "eFlow" nebulizer, including the associated technology and intellectual property, for the clinical development, registration and commercialization of Inhaled AAT for two additional indications of lung disease, namely cystic fibrosis and bronchiectasis. Pursuant to the addendum, each party will be responsible for developing and adapting its own product for the additional indications and will bear the costs involved. Additionally, we and PARI will supply, each at its own expense, Inhaled AAT and the "eFlow" nebulizers, respectively, and in the quantities required for all phases of clinical studies worldwide for the additional indications. In addition, PARI will provide us, at its expense, technical and regulatory support regarding the "eFlow" nebulizer. Sales of the inhaled formulation of AAT for the additional indications will entitle PARI to royalty payments as provided in the Original PARI Agreement. We are currently not progressing the development of Inhaled AAT for the additional indications.

The PARI Agreement expires when the PARI Royalties Period ends. Either party can terminate the PARI Agreement upon customary termination provisions. Additionally, upon the occurrence of any one of the following events, PARI has the right to negotiate with us in good faith about whether to continue our collaboration: (i) PARI's costs of the required clinical trials exceed a certain amount, unless we or a third party incurs such expenses on behalf of PARI; (ii) an inhaled formulation of AAT is not successfully registered with any regulatory authorities by 2016; (iii) there are no commercial sales of inhaled formulations of AAT within a certain period after successful registration with any regulatory authority; or (iv) we cease development of inhaled formulations of AAT for a certain period of time. If, within 180 days of PARI's request to negotiate, we do not agree to continue the collaboration, PARI has the option either to render the license they grant to us non-exclusive or to terminate the agreement. We have the right to terminate the agreement, upon prior written notice, (i) in the event that the "eFlow" nebulizer is determined to infringe upon a third party's intellectual property rights, (ii) an injunction barring the use of the "eFlow" nebulizer has been in place for a certain period of time, (iii) a clinical trial for inhaled formulations of AAT fails as a result of, after a cure period, the "eFlow" nebulizer not conforming to specifications or PARI's inability to supply the "eFlow" nebulizer; or (iv) failure by PARI to register the "eFlow" nebulizer within a certain period of time after receiving Phase 3 results for Inhaled AAT for AATD. Following any termination, all licensed rights will revert to PARI, unless we terminate the agreement as a result of PARI's bankruptcy, payment failure or material breach, in which case we retain the license rights to the "eFlow" nebulizer as long as we continue making royalty payments.

On February 21, 2008, we also signed a commercialization and supply agreement with PARI that provides for the commercial supply of the "eFlow" nebulizer and its spare parts to patients who may be treated with the inhaled formulation of AAT, if approved, either through its own distributors, our distributors or independent distributors in countries where PARI does not have a distributor. The commercialization and supply agreement expires upon the earlier of (1) the end of four years from (x) the end of the last PARI Royalties Period, or (y) the termination of the PARI Agreement by one party due to the other party declaring bankruptcy, failing to make a payment after a 30-day cure period or breach of a material provision after a 30-day cure period, or (2) the termination of the PARI Agreement pursuant to its terms, other than for reasons as previously described, in which case the commercialization and supply agreement terminates simultaneously with the PARI Agreement provided that PARI ensures availability of the "eFlow" nebulizer and its associated spare parts and service to anyone being treated with the inhaled formulation of AAT at the time of such termination, for the warranty period of the device or for a longer period, if required by the applicable law or the relevant regulatory authority.

In May 2019, we signed a Clinical Study Supply Agreement ("CSSA") with PARI for the supply of the required quantities of PARI's "eTrack" controller kits and the "PARItrack" web portal associated with PARI's "eFlow" nebulizer required for our pivotal Phase 3 InnovAATe clinical trial and for the FDA required HFS. The CSSA is a supplement agreement to the PARI Agreement and will expire upon the expiration or termination of the PARI Agreement.

Manufacturing and Supply

We have a production plant located in Beit Kama, Israel. We currently manufacture six of our proprietary plasma-derived commercial products, including three FDA approved products, in this facility: KEDRAB/KAMRAB, CYTOGAM, GLASSIA, KAMRHO (D), and two types of the snake bite antiserum product. We also manufacture at our plant the investigational Inhaled AAT product.

In December 2022, we submitted an application to the FDA, and in May 2023, we received FDA's approval to manufacture CYTOGAM at our facility in Beit Kama, Israel. Following FDA's approval, CYTOGAM manufactured at our Israeli facility has been available for commercial sale in the United States since October 2023. The FDA approval represents the successful conclusion of the technology transfer process of CYTOGAM from the previous manufacturer, CSL Behring. In July 2023, we also received the approval of Health Canada to manufacture CYTOGAM at our facility, following a technology transfer application that we submitted in January 2023. As part of the CYTOGAM technology transfer process, we engaged Prothya as a third-party contract manufacturer to perform certain manufacturing activities required for the manufacturing of CYTOGAM. In addition, we assumed from Saol a plasma supply agreement with CSL Behring for continued supply of the required plasma for the manufacturing of the product.

We operate our Beit Kama production facility on a campaign-basis so that at any time the facility is assigned to produce only one product. The utilization of the facility's production capacity among the various products is determined based on orders received, sales forecasts and development needs. During each year we conduct routine maintenance shutdowns of our plant, which may last up to a few weeks. In addition, we periodically invest in upgrading infrastructures and adjusting capacity needs.

Our production plant passed various health authorities' inspections. The plant was initially inspected by the U.S. FDA during 2010. In March 2017, the FDA completed inspections of our facility in connection with our GLASSIA and KEDRAB products, with no critical observations. As part of the recently approved PAS (Prior Approval Supplement) submitted to the FDA with respect to CYTOGAM manufacturing at our Beit Kama facility, the plant underwent an FDA site inspection during the first quarter of 2023, which concluded with no critical observations. The Israeli MOH conducted a GMP inspection in each of 2011, July 2013, February 2016, November 2018, December 2020 and December 2022, which concluded with no critical observations. In July 2018, Health Canada completed an inspection in connection with KAMRAB registration in Canada, with no critical observations. In May 2023, Health Canada completed a remote inspection in connection with the CYTOGAM technology transfer application, with no critical observations. In February 2019, the Croatian (part of the EU) health agency completed a GMP inspection of our facility in connection with GLASSIA and our Inhaled AAT product, with no critical observations. In March 2019, the Mexican Health Agency completed a GMP inspection of our facility in connection with our KAMRAB registration in Mexico, with no critical observations, and with a dispute on required corrective actions. The Kazakhstan health agency also completed a GMP inspection in April 2019, with no critical observations.

Any changes in our production processes related to our Proprietary Products must be approved by the FDA and/or similar authorities in other jurisdictions. From time to time, we make certain required modifications to our manufacturing process and are required to make certain filings to report such changes to the FDA and/or other similar authorities.

HEPAGAM B, VARIZIG and WINRHO SDF, which we acquired in November 2021, are currently manufactured by Emergent under a manufacturing services agreement we assumed as part of the acquisition of the portfolio from Saol. Under the agreement, Emergent serves as our exclusive manufacturer of the three products. The manufacturing services are performed at Emergent's facilities in Winnipeg, Canada. The current agreement is in effect until September 27, 2027, and may be terminated without cause by us upon at least two years advance notice or immediately in the event of a manufacturing failure (as defined in the agreement). Emergent may terminate the agreement upon at least three years advance notice. We expect to continue manufacturing these products by Emergent in the foreseeable future and are also considering the initiation of a technology transfer for transitioning the manufacturing of these products to our manufacturing facility in Beit Kama, Israel. The initiation of such a technology transfer would be subject to executing a new, amended manufacturing services agreement with Emergent covering operational aspects and the technology transfer related services and scope. We anticipate that once initiated, such technology transfer may be completed within four to five years.

Raw Materials

The main raw materials in our Proprietary Products segment are hyper-immune plasma and fraction IV derived from normal source plasma. We also use other raw materials, including both natural and synthetic materials. We purchase raw materials from suppliers who are regulated by the FDA, EMA and other regulatory authorities. Our suppliers are approved in their countries of origin and by the IMOH. The raw materials must comply with strict regulatory requirements. We require our raw materials suppliers to comply with the cGMP regulations, and we audit our suppliers from time to time. We are dependent on the regular supply and availability of raw materials in our Proprietary Products segment.

We maintain relationships with several suppliers to ensure availability and reduce reliance on specific suppliers. We are dependent, however, on several suppliers who supply specialty ancillary products prepared for the production process, such as specific gels and filters. See "Item 3. Key Information — D. Risk Factors — *We would become supply-constrained and our financial performance would suffer if we were unable to obtain adequate quantities of source plasma or plasma derivatives or specialty ancillary products approved by the FDA, the EMA, Health Canada or the regulatory authorities in Israel, or if our suppliers were to fail to modify their operations to meet regulatory requirements or if prices of the source plasma or plasma derivatives were to raise significantly*."

In the years ended December 31, 2023, 2022 and 2021, we incurred $19.9 million, $13.1 million and $16.7 million of expenses for the purchase of main raw materials, respectively. The increase in main raw materials' purchase costs was in support of increased manufacturing to meet the increased sales.

Hyper-immune Plasma

We have a number of suppliers in the United States for hyper-immune plasma with which we have long-term supply agreements. Hyper-immune plasma is used for the production of KEDRAB/KAMRAB, CYTOGAM, WINRHO SDF, VARIZIG, HEPGAM B and KAMRHO (D). In addition to long-term supply agreements, we work to secure availability of hyper-immune plasma on an annual basis by providing forecasts to our suppliers based on our customers' actual and forecasted demand. We continue to seek new long-term supply agreements for hyper-immune plasma with additional plasma-collection companies.

In January 2012, we entered into a plasma purchase agreement with Kedplasma, a subsidiary of Kedrion, for the supply of anti-rabies hyper-immune plasma required for the manufacturing of KAMRAB (including for manufacturing of KEDRAB for sale to Kedrion for further distribution in the U.S. market). The agreement provides for a commitment to supply certain minimum annual quantities at predetermined prices. The agreement is renewed every three years, and the parties agree on quantity and pricing terms in each renewal period. We have an additional U.S.-based supplier of anti-rabies hyper-immune plasma, and we also received in 2023 FDA approval and initiated the collection of anti-rabies plasma at our Kamada Plasma collection center.

CMV hyper-immune plasma for the manufacturing of CYTOGAM is supplied by CSL Behring, initially under a three-year supply agreement that we assumed from Saol, and in December 2023, we entered into a plasma supply agreement directly with CSL Behring that supersedes the assumed supply agreement and provides for the continued supply of required plasma for the manufacturing of the product for each of the years 2024-2026.

Emergent is currently responsible for securing the hyper-immune plasma from different plasma suppliers for the manufacturing of HEPAGAM B, VARIZIG and WINRHO SDF, pursuant to our manufacturing services agreement with Emergent (see above— "Manufacturing and Supply").

Plasma derived Fraction IV paste for GLASSIA manufacturing

On August 23, 2010, in conjunction with the partnership arrangement with Baxter (now Takeda), we signed a fraction IV paste supply agreement with Baxter (now Takeda) for the supply of fraction IV for use in the production of GLASSIA to be sold in the United States. Under this agreement, Takeda also supplies us with fraction IV to continue the development, pre-clinical and clinical studies of GLASSIA and other AAT derived products and for the production, sale and distribution of GLASSIA in jurisdictions other than those which are covered under the exclusive manufacturing, supply and distribution agreement with Takeda as well as for other AAT derived products. Takeda did not receive payment for the supply of fraction IV plasma used by us for the manufacture of GLASSIA sold to Takeda through 2021. If we require fraction IV for other purposes, we are entitled to purchase it from Takeda at a predetermined price. The supply agreement terminates on August 23, 2040, subject to an option for earlier termination in the event of a material breach.

We have an additional fraction IV plasma supplier, approved for production of GLASSIA marketed in non-U.S. countries.

For information related to our internal plasma collection capabilities, see above "*Plasma Collection.*"

Marketing and Distribution

We distribute our Proprietary products in more than 30 countries world-wide including the U.S., Canada, Russia, Argentina, Israel, India, Turkey, Australia, Switzerland, Poland, Romania and several other countries in Europe, Latin America, Asia, and the MENA region. We are also a supplier of PAHO, the specialized international health agency for the Americas. We distribute our products in these markets directly or through strategic partners (e.g., Kedrion in the U.S. market) and or by local distributers. We typically receive orders for our products and receive requests for participation in tenders for the supply of our products from our existing distributors as well as from new potential distributors.

We sell KEDRAB to Kedrion for distribution in the U.S. market and sell KAMRAB and KAMRHO (D) to other distributers in non-U.S. countries. Through 2021, we sold GLASSIA to Takeda for further distribution in the U.S. market and we sell the product to other distributors in non-U.S. countries. In the Israeli market, we sell and distribute GLASSIA, KAMRAB and KAMRHO (D) independently to local HMOs and medical centers, or through a third-party logistic partner that specializes in the supply of equipment and pharmaceuticals to healthcare providers, and in addition we sell our anti-snake venom to the IMOH.

We distribute CYTOGAM, HEPAGAM B, VARIZIG and WINRHO SDF in the U.S. market directly to wholesalers and local distributors, through our wholly owned U.S. subsidiary, Kamada Inc. Through August 2022, and pursuant to the terms of the transition services agreement, we relied on Saol to manage and oversee the U.S. distribution of these products. Commencing September 2022, we assumed all distribution responsibilities for these products in the U.S. market and are utilizing a U.S. 3PL provider for storage, logistics and distribution, which provides complete order to cash services. We are also responsible for marketing activities, price determination, provision of rebates and credits as well as mandatory pricing reporting requirements for these products in the U.S. market. We distribute these products in non-U.S. countries, primarily Canada and the MENA region, through engagement of local distributors.

We continue to leverage our existing strong international distribution network to expand the sales of CYTOGAM, HEPAGAM B, VARIZIG and WINRHO SDF to existing markets we currently operate in and furthermore, we intend to explore the expansion of sales of our products, primarily GLASSIA and KAMRAB to the new international markets we assumed following the acquisition of the new product portfolio, primarily in the MENA region.

In 2022, we deployed an experienced team of U.S.-based sales and medical affairs professionals who established our operations in this key market. The U.S. sales team promotes our portfolio of specialty plasma-derived IgG products to physicians and other healthcare practitioners through direct engagement and opportunities at medical conventions. The medical affairs team educates physicians by addressing their scientific and clinical inquiries, along with participating in major medical conferences. Our activities promoting these important therapies, primarily CYTOGRAM and VARIZIG, represent the first time in over a decade that these hyper-immune specialty products have been supported by field-based activity in the U.S. We are encouraged by the consistently positive feedback received from key U.S. physicians who are seeking to publish new clinical data related to our products, while conducting educational symposiums that we believe will have a positive impact on the understanding of these medicines, contributing to continued growth in demand.

Our promotional activities, including engagements with healthcare practitioners, are conducted in compliance with the FDA's restrictions on promotion of pharmaceuticals, including the Anti-Kickback statutes.

Outside the U.S. market, our distributors sell our products through a tender process and/or the private market. The tender process is conducted on a regular basis by the distributors, sometimes on an annual basis. For existing distributors, our existing relationship does not guarantee additional orders in these tenders. The decisive parameter is generally the price proposed in the tender. The distributor purchases products from us and sells them to its customers (either directly or by means of sub-distributors). In most cases, we do not sign agreements with the end users, and as such, we do not fix the price to the end user or its terms of payment and are not exposed to credit risks of the end users. In the vast majority of cases, our agreements with the local distributors award the various distributors exclusivity in the distribution of our products in the relevant country, if permitted. The distribution agreements are usually made for a specific initial period and are subsequently renewed for certain agreed periods, where the parties have the right to cancel or renew the agreements with prior notice of several months. In these markets, we do not actively participate in the marketing to the end users, except for supplying marketing assistance where the cost is negligible or in some cases, reimburse the local distributor for an agreed amount of its actual marketing expenses.

We are establishing our footprint in the MENA region as a leader in the specialty plasma-derived field by exploring geographical expansion opportunities and strengthening our relationships with KOLs across the region. Furthermore, we capitalize on our strong regulatory affairs capabilities to register our products with the relevant authorities to ensure proper and fast market access.

Most of our sales outside of Israel are made against open credit and some in documentary credit or advance payment. Most of our sales inside Israel are made against open credit or cash. The credit given to some of our customers abroad (except for sales in documentary credit or advanced payment) is mostly secured by means of a credit insurance policy and in certain cases with bank guarantees.

In the Distribution segment, we market our products in Israel to HMOs and hospitals on our own or through third party logistic associates. We sell certain of our Distribution products through offers to participate in public tenders that occur on an annual basis or through direct orders. The public tender process involves HMOs and hospitals soliciting bids from several potential suppliers, including us, and selecting the winning bid based on several attributes, the primary attributes are generally price and availability. The annual public tender process is also used by our existing customers to determine their suppliers. As a result, our existing relationship with customers in our Distribution segment does not guarantee additional orders from such customers year over year.

To secure supply of our products in the Distribution segment, we enter into supply and distribution agreements with the product owners , pursuant to which we undertake to register the products with the IMOH, acquire certain quantity of products and act as the product distributor in the Israeli market. We work closely with those suppliers to develop annual forecasts, but these forecasts usually do not obligate our suppliers to provide us with their products.

Customers

For the year ended December 31, 2023, sales to our three largest customers, Kedrion, Takeda and Clalit Health Services, an Israeli HMO, accounted for 23%, 11% and 7%, respectively, of our total revenues. For the years ended December 31, 2022 and 2021, sales to our three largest customers, Takeda, Kedrion and Clalit Health Services, accounted for 13%, 11% and 9% and 31%, 12% and 12%, respectively, of our total revenues.

While Kedrion, Takeda and Clalit Health Services continue to be our major customers, other key customers in the segment include McKesson and Cardinal Health, two of the largest U.S. based wholesalers, PAHO, two Canadian customers and our distributors in Argentina, Russia, Thailand, India, Brazil, the MENA region and other territories. These arrangements are further described above under "— Marketing and Distribution."

Our primary customers in the Distribution segment in Israel are HMOs, including Clalit Health Services and Maccabi Healthcare Services, Israeli hospitals and the IMOH.

Seasonality

We have experienced in the past, and may experience in the future, certain fluctuations in our quarterly revenues.

Competition

The worldwide market for pharmaceuticals in general, and biopharmaceutical and plasma derived products, in particular, has, in recent years, undergone a process of consolidation through mergers and acquisitions. This trend has led to a reduction in the number of competitors and the strengthening of the remaining companies, particularly in the plasma-derived sector.

Proprietary Products Segment

There are a limited number of direct competitors for each of our products in the Proprietary Products segment. These competitors include CSL Behring, Grifols (which acquired Biotest AG during 2022), Kedrion (other than for KEDRAB) (which merged with BPL during 2022), and ADMA Biologics Inc. Most of these companies are multinational corporations that specialize in plasma derived protein therapeutics and are distributing their plasma derived pharmaceutical products worldwide. We have not seen significant changes in the activities of our competitors in recent years. Additionally, our strategic alliance with Kedrion in the United States has strengthened our KEDRAB competitive positioning in the market. The acquisition of Biotest by Grifols and the merger between Kedrion and BPL might impact the markets that we operate in. In some international markets, such as India, Thailand and Russia, we also have local competitors for KAMRAB and KAMRHO (D).

In addition, we face potential competition from other biopharmaceutical companies that develop and market non-plasma derived products that are approved for similar indications as our Proprietary products.

In cases of existing competition, our competitors usually have advantages in the market because of their size, financial resources, plasma-collection capacity, and the duration of their activities and experience in the relevant market, especially in the United States and countries of the European Union.

The following describes details known to us about our most significant competitors for each of our main Proprietary Products segment products.

KEDRAB/KAMRAB. We believe that there are two main competitors for this anti-rabies IgG product worldwide: Grifols, whose product we estimate comprises the majority of the anti-rabies IgG market in the United States, and CSL Behring, which sells its anti-rabies product in Europe and other international markets. Sanofi Pasteur, the vaccines division of Sanofi S.A., exited the U.S. anti-rabies IgG market as well as some additional international markets during 2022. We believe that such departure, among other things, contributed to the increase in demand for KEDRAB in the United States. in 2023. BPL, which has an anti-Rabies IgG product for the UK market, has developed it also for the U.S. market, including performing a clinical trial; however, it did not complete the product development and has not submitted a BLA for FDA approval. in light of the recent business combination of Kedrion and BPL, as well as the recent binding memorandum of understanding we entered into with Kedrion, we do not anticipate that the product development will be continued. There are several local producers in other countries that make anti-rabies IgG products, mostly based on equine serum, which we believe results in inferior products, as compared to products made from human plasma. Over the past several years, several companies have made attempts, and some are still in the process of developing monoclonal antibodies for anti-rabies treatment. The first monoclonal antibody product was approved and is available in India. These products may be as effective as the currently available plasma derived anti-rabies immunoglobulin and may potentially be cheaper, and as such may result in the future in increased competition and potential loss of market share of KEDRAB/KAMRAB.

CYTOGAM. To our knowledge, CYTOGAM is the only plasma derived CMV IgG product approved in the United States and Canada. In Europe and other international markets Cytotec CP/Megalotect (Biotest), a plasma derived competing product, is available. Based on available public information, the FDA approved the following non-plasma derived antiviral drugs for the prevention of CMV infection and disease: Letermovir (Prevymis), developed by Merck& Co., and for treatment of refractory/resistant infection or disease Maribavir (Livtencity), developed by Takeda. Since their launch, these products have resulted in the loss of market share for CYTOGAM. Currently, treatment guidelines state that combination therapy with standard antiviral can be considered for certain solid organ transplant recipients. The most used antivirals are Ganciclovir (Cytovene-IV Roche) and Valgnciclovir (Valcyte Roche). Patients treated with such antivirals agents for a long time can develop resistance and will require a second-line treatment such as Foscarnet (Foscavir Pfizer) or Cidofovir (Gilead Sciences). Despite the introduction of newer antiviral therapies for CMV in solid organ transplantation, there is a growing need to determine the optimal approach of CMV management when considering all available therapies, including CYTOGAM.

WINRHO SDF. WINRHO SDF is an Anti-D IgG product (also called Rh_o(D) IgG) which in registered in the United States competes with corticosteroids (oral prednisone or high-dose dexamethasone) or IVIG (Grifols, CSL Behring and Takeda are the main IVIG manufacturers and suppliers in the U.S.) as first or second line treatment for acute ITP, with IVIG or WINRHO SDF recommended for pediatric patients in whom corticosteroids are contraindicated. Rhophylac, a competing Anti-D IgG of CSL Behring is also approved for ITP treatment, but we believe it is mostly used for HDN, due to its comparatively small vial size. Outside the U.S., WINRHO SDF is used for HDN indication. The market in Ex-US countries is usually led by tenders, where key indicators are registration status and price. Our main competitors in those countries are RhoGAM (Kedrion), Hyper RHO (Grifols) and Rhophylac (CSL Behring). Our KAMRHO (D) is a similar product to WINRHO SDF, however, since the two products are registered in different countries, they do not directly compete.

HEPAGAM B. To our knowledge, in the United States HEPAGAM B is the only approved HBIG with an on-label indication for Liver Transplants. To our understanding, HEPAGAM B holds the majority market share for the indication, while another HBIG (Nabi-HB manufactured and supplied by ADMA) is being used off-label by some medical centers for the indication. In recent years the duration of HBIG treatment has been reduced by physicians. New generation antivirals are considered effective for preventing HBV reactivation post-transplant, reducing HBIG use. PEP indication in the United States is covered almost totally by Nabi-HB (ADMA) and HyperHEP (Grifols). In Canada, the main competition in national tenders is HypeHEP. In ROW territories, such as Turkey, the MENA region, and in Israel, HEPATECT CP and Zutectra (Biotest AG) represent the main competition.

VARIZIG. To our knowledge, VARIZIG is the only plasma derived Varicella-Zoster IgG product approved in the United States and Canada. In Europe and other international markets VARITECT (Biotest AG) and additional plasma derived competing products are available. In the United States, incidence of VZV infection has decreased significantly since the introduction of the varicella vaccine in 1995. Although the use of the vaccine has reduced the frequency of chickenpox, the virus has not been eradicated. Moreover, incidence of Herpes Zoster, also caused by VZV, is increasing among adults in the United States. Suboptimal vaccination rates contribute to outbreaks and increased risk of VZV exposure. Immunocompromised population and other patient groups are at high risk for severe varicella and complications, after being exposed to VZV. VARIZIG is recommended by the CDC for post-exposure prophylaxis of varicella for persons at high risk for severe disease who lack evidence of immunity to varicella. Alternative CDC recommendations include IVIG if VARIZIG is unavailable and some experts recommend using Acyclovir, Valacyclovir, although published data on the benefits of Acyclovir as post-exposure prophylaxis among immunocompromised people are limited.

GLASSIA. There are several competing products to GLASSIA. Grifols, CSL Behring and Takeda have competing plasma derived AAT products approved for AATD that are marketed in the U.S., Canada as well as in some European countries. We estimate that Prolastin, Grifols' AAT infusion product for the treatment of AATD, accounts for at least 50% market share in the United States and more than 70% of sales worldwide. In September 2017, Grifols announced FDA approval of a liquid formulation of Prolastin, and to the best of our knowledge, Grifols's liquid product is only sold in the U.S. market. Grifols is also a producer of an additional AAT product, Trypsone, which is marketed in Spain and in some Latin American countries, including Brazil. CSL Behring's AAT by IV product, Zemaira, is mainly sold in the United States, and during 2015 received centralized marketing authorization approval in the European Union. CSL Behring launched the product in a few selected EU markets during 2016 under the brand name Respreeza. Takeda is our strategic partner for sales of GLASSIA and it also serves existing patients in the United States with its own proprietary AAT product, Aralast. As far as we know, Takeda is selling both products in the United States, and maintaining existing patients on Aralast. Laboratoire Français du Fractionnement et des Biotechnologies, S.A. (LFB) is a producer of an AAT product distributed only in the French market. We do not believe that new plasma derived AAT products are expected to enter the U.S. market in the near future.

There are several other competitors in pre-clinical and clinical stage such as Inhibrx, Mereo, ApicBio and Vertex Pharmaceuticals, all of which have development programs for new medications for treatment of AATD lung disease. Based on available public information, Inhibrx, a California based company, is in clinical development of INBRX-101 a recombinantly produced AAT protein specifically designed to address some limitations of the current stand of care plasma derived AAT augmentation therapy. The modifications introduced into INBRX-101 aim to improve the pharmacokinetic profile (PK) and obliterate inactivation through oxidation. This could offer superior clinical activity to the current commercial plasma derived IV AAT by providing sustained enhanced serum concentration with a less frequent dosing regimen. In January 2024, Inhibrx and Sanofi announced that the companies have entered into a definitive agreement under which Aventis Inc., a subsidiary of Sanofi, will acquire all the assets and liabilities associated with INBRX-101, which was indicated to be in a registrational trial for the treatment of patients with alpha-1 antitrypsin deficiency. Mereo, a UK based company, completed phase 2 development of MPH-966 as an oral neutrophil elastase inhibitor being explored for the potential treatment of AATD, and is currently discussing the regulatory pathway for phase 3 development with the regulatory authorities. Vertex, a Boston, MA headquartered company, is in early development of a small molecule folding corrector. Vertex believes small molecule correctors for protein misfolding could address both liver and lung disease manifestations, possibly avoiding the need for conventional augmentation therapy, further differentiating its product candidates as a novel therapeutic approach. Clinical development of the corrector candidate VX-864 was discontinued. Other corrector candidate(s) are at the pre-clinical stages. Wave therapeutics, which secured a licensing deal with GSK, announced that its candidate RNA-editing molecule WVE-006, designed to restore production and circulation of functional, wild-type AAT protein and reduce levels of mutant Z-AAT protein, is entering clinical development and addressing AATD -related lung disease, liver disease or both. Other companies pursuing gene therapy modalities include Intellia Therapeutics, ADARx and Apic Bio. These product candidates, if approved, may have an adverse effect on the AATD market size and reduce or eliminate the need for the currently approved plasma derived AAT augmentation therapy, and thus may affect our ability to continue and generate revenues and earnings from GLASSIA. In addition, these product candidates, if approved, may have a negative effect on our ability to continue the development of our Inhaled AAT, and if approved, to market Inhaled AAT and obtain a meaningful market share.

KAMRHO(D). We market KAMRHO (D) for HDN, mainly in, Israel, Argentina and Chile. Kedrion is one of our competitors for KAMRHO(D) in some of those international markets. We believe there are currently two additional main suppliers of competitive products, Grifols and CSL Behring. There are also local producers in other countries that make similar products mostly intended for local markets.

Distribution Segment

There are several companies active in the Israeli market distributing the products of several manufacturers whose comparable products compete with the products we distribute as part of our Distribution segment. In the plasma area, these manufacturers include Grifols, Takeda and CSL Behring. In other specialties and biosimilar products, we are competing with products produced by some of the largest pharmaceutical companies in the world, such as Novartis AG, AstraZeneca AB, Sanofi and GlaxoSmithKline. These competing manufacturers have advantages of size, financial resources, market share, broad product selection and extensive experience in the market, although we believe that we have established strong expertise in the Israeli market to support our market access efforts and take a significant market share. Each of these competitors sells its products through a local subsidiary or a local representative in Israel.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we sell and are developing. Except for compassionate use or non-registered named-patient cases, any pharmaceutical candidate that we develop must be approved by the FDA before it may be legally marketed in the United States and by the appropriate regulatory agencies of other countries before it may be legally marketed in such other countries. In addition, any changes or modifications to a product that has received regulatory clearance or approval that could significantly affect its safety or effectiveness or would constitute a major change in its intended use, may require the submission of a new application in the United States and/or in other countries for pre-market approval. The process of obtaining such approvals can be expensive, time consuming and uncertain.

U.S. Drug Development Process

In the United States, pharmaceutical products are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act and other laws, including, in the case of biologics, the Public Health Service Act. All of our products for human use and product candidates in the United States, are regulated by the FDA as biologics. Biologics require the submission of a BLA and approval or license by the FDA prior to being marketed in the United States. Manufacturers of biologics may also be subject to state regulation. Failure to comply with regulatory requirements, both before and after product approval, may subject us and/or our partners, contract manufacturers and suppliers to administrative or judicial sanctions, including FDA delay or refusal to approve applications, warning letters, product recalls, product seizures, import restrictions, total or partial suspension of production or distribution, fines and/or criminal prosecution.

The steps required before a biologic drug may be approved for marketing for an indication in the United States generally include:

1. preclinical laboratory tests and animal tests;
2. submission to the FDA of an IND application for human clinical testing, including required CMC sections, which must become effective before human clinical trials may commence;
3. adequate and well-controlled human clinical trials to establish the safety and efficacy of the product;
4. submission to the FDA of a BLA or supplemental BLA, with all the required information;
5. FDA pre-approval inspection of product manufacturers; and
6. FDA review and approval of the BLA or supplemental BLA.

Preclinical studies include laboratory evaluation, as well as animal studies to assess the potential safety and efficacy of the product candidate. Preclinical safety tests must be conducted in compliance with FDA regulations regarding good laboratory practices. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND which must become effective before human clinical trials may be commenced. The IND will automatically become effective 30 days after receipt by the FDA, unless the FDA before that time raises concerns about the drug candidate or the conduct of the trials as outlined in the IND. The IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. There can be no assurance that submission of an IND will result in FDA authorization to commence clinical trials or that, once commenced, other concerns will not arise that could lead to a delay or a hold on the clinical trials.

Clinical trials involve the administration of the investigational product to healthy volunteers or to patients, under the supervision of qualified principal investigators. Each clinical study at each clinical site must be reviewed and approved by an independent institutional review board, prior to the recruitment of subjects. Numerous requirements apply including, but not limited to, good clinical practice regulations, privacy regulations, and requirements related to the protection of human subjects, such as informed consent.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap and different trials may be initiated with the same drug candidate within the same phase of development in similar or differing patient populations.

- Phase 1 studies may be conducted in a limited number of patients, but are usually conducted in healthy volunteer subjects. The drug is usually tested for safety and, as appropriate, for absorption, metabolism, distribution, excretion, pharmacodynamics and pharmacokinetics.

- Phase 2 usually involves studies in a larger, but still limited, patient population to evaluate preliminarily the efficacy of the drug candidate for specific, targeted indications; to determine dosage tolerance and optimal dosage; and to identify possible short-term adverse effects and safety risks.

- Phase 3 trials are undertaken to further evaluate clinical efficacy of a specific endpoint and to test further for safety within an expanded patient population at geographically dispersed clinical study sites.

Phase 1, Phase 2 or Phase 3 testing may not be completed successfully within any specific time period, if at all, with respect to any of our product candidates. Results from one trial are not necessarily predictive of results from later trials, the FDA may require additional testing or a larger pool of subjects beyond what we proposed as the clinical development process proceeds, thereby requiring more time and resources to complete the trials. Furthermore, the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk, or may not allow the importation of the clinical trial materials if there is non-compliance with applicable laws.

The results of the preclinical studies and clinical trials, together with other detailed information, including information on the manufacture and composition of the product, are submitted to the FDA as part of a BLA requesting approval to market the product candidate for a proposed indication. Under the Prescription Drug User Fee Act, as amended, the fees payable to the FDA for reviewing a BLA, as well as annual fees for commercial manufacturing establishments and for approved products, can be substantial. The BLA review fee alone can exceed $3,200,000, subject to certain limited deferrals, waivers and reductions that may be available. Each BLA submitted to the FDA for approval is typically reviewed for administrative completeness and reviewability within 45 to 60 days following submission of the application. If found complete, the FDA will "file" the BLA, thus triggering a full review of the application. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission. The FDA's established goals are to review and act on 90% of priority BLA applications and priority original efficacy supplements within six months of the 60-day filing date and receipt date, respectively. The FDA's goals are to review and act on 90% of standard BLA applications and standard original efficacy supplements within 10 months of the 60-day filing date and receipt date, respectively. The FDA, however, may not be able to approve a drug within these established goals, and its review goals are subject to change from time to time. Further, the outcome of the review, even if generally favorable, may not be an actual approval but an "action letter" that describes additional work that must be done before the application can be approved. Before approving a BLA, the FDA may inspect the facilities at which the product is manufactured or facilities that are significantly involved in the product development and distribution process, and will not approve the product unless cGMP compliance is satisfactory. The FDA may deny approval of a BLA if applicable statutory or regulatory criteria are not satisfied, or may require additional testing or information, which can delay the approval process. FDA approval of any application may include many delays or never be granted. If a product is approved, the approval will impose limitations on the indicated uses for which the product may be marketed, will require that warning statements be included in the product labeling, may impose additional warnings to be specifically highlighted in the labeling (e.g., a Black Box Warning), which can significantly affect promotion and sales of the product, may require that additional studies be conducted following approval as a condition of the approval, may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. To market a product for other uses, or to make certain manufacturing or other changes requires prior FDA review and approval of a BLA Supplement or new BLA. Further post-marketing testing and surveillance to monitor the safety or efficacy of a product is required. Also, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if safety or manufacturing problems occur following initial marketing. In addition, new government requirements may be established that could delay or prevent regulatory approval of our product candidates under development.

As part of the Patient Protection and Affordable Care Act (the "healthcare reform law"), Public Law No. 111-148, under the subtitle of Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), a statutory pathway has been created for licensure, or approval, of biological products that are biosimilar to, and possibly interchangeable with, earlier biological products approved by the FDA for sale in the United States. Also under the BPCIA, innovator manufacturers of original reference biological products are granted 12 years of exclusive use before biosimilars can be approved for marketing in the United States. There have been proposals to shorten this period from 12 years to seven years. The objectives of the BPCI are conceptually similar to those of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the "Hatch-Waxman Act," which established abbreviated pathways for the approval of drug products. A biosimilar is defined in the statute as a biological product that is highly similar to an already approved biological product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biosimilar and the approved biological product in terms of the safety, purity, and potency. Under this approval pathway, biological products can be approved based on demonstrating they are biosimilar to, or interchangeable with, a biological product that is already approved by the FDA, which is called a reference product. If we obtain approval of a BLA, the approval of a biologic product biosimilar to one of our products could have a significant impact on our business. The biosimilar product may be significantly less costly to bring to market and may be priced significantly lower than our products.

Both before and after the FDA approves a product, the manufacturer and the holder or holders of the BLA for the product are subject to comprehensive regulatory oversight. For example, quality control and manufacturing procedures must conform, on an ongoing basis, to cGMP requirements, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to spend time, money and effort to maintain cGMP compliance. In addition, a BLA holder must comply with post-marketing requirements, such as reporting of certain adverse events. Such reports can present liability exposure, as well as increase regulatory scrutiny that could lead to additional inspections, labeling restrictions, or other corrective action to minimize further patient risk.

Special Development and Review Programs

Orphan Drug Designation

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States and there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the United States. In the United States, orphan drug designation must be requested before submitting a BLA or supplemental BLA.

In the European Union, the Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union community. Additionally, this designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product.

We received an orphan drug designation in the United States and Europe for multiple indications. Inhaled AAT for AATD has received an orphan drug designation in the United States and Europe. The inhaled formulation of AAT for the treatment of cystic fibrosis has received an orphan drug designation in the United States and Europe. The inhaled formulation of AAT for the treatment of bronchiectasis has received an orphan drug designation in the United States. The additional indication for GLASSIA for the treatment of newly diagnosed cases of Type-1 Diabetes has received an orphan drug designation in the United States. In addition, the indication for AAT for the treatment of Graft versus Host Disease has received an orphan drug designation in the United States and Europe, and the indication for AAT for the treatment of Prophylactic Graft versus Host Disease has received an orphan drug designation in the United States.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product and its active ingredients receive the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. In addition, the FDA may rescind orphan drug designation and, even with designation, may decide not to grant orphan drug exclusivity even if a marketing application is approved. Furthermore, the FDA may approve a competitor product intended for a non-orphan indication, and physicians may prescribe the drug product for off-label uses, which can undermine exclusivity and hurt orphan drug sales. There has also been litigation that has challenged the FDA's interpretation of the orphan drug exclusivity regulatory provisions, which could potentially affect our ability to obtain exclusivity in the future.

In the European Union, orphan drug designation also entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity or a safer, more effective or otherwise clinically superior product is available.

In the European Union, an application for marketing authorization can be submitted after the application for orphan drug designation has been submitted, while the designation is still pending, but should be submitted prior to the designation application in order to obtain a fee reduction. Orphan drug designation does not convey any advantage in, except eligibility to conditional approval process, or shorten the duration of, the regulatory review and approval process.

Post-Approval Requirements

Any drug products for which we receive FDA approvals are subject to continuing regulation by the FDA. Certain requirements include, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information on an annual basis or more frequently for specific events, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. These promotion and advertising requirements include, among others, standards for direct-to-consumer advertising, prohibitions against promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), and other promotional activities. We are also required to ensure that non-promotional scientific exchanges concerning our products are truthful and non-misleading. Failure to comply with FDA requirements can have negative consequences, including the immediate discontinuation of noncomplying materials, adverse publicity, warning letters from or other enforcement by 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. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not encourage, market or promote such off-label uses.

The manufacturing of our product candidates is required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. Our product candidates are either manufactured at our production plant in Beit Kama, Israel, or, for products where we have entered into a strategic partnership with a third party to cooperate on the development of a product candidate, at a third-party manufacturing facility. These regulations require, among other things, quality control and quality assurance, as well as the corresponding maintenance of comprehensive records and documentation. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are also required to register their establishments and list any products they make with the FDA and to comply with related requirements in certain states. These entities are further subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in serious and extensive restrictions on a product, manufacturer or holder of an approved new drug application (NDA) or BLA, as well as lead to potential market disruptions. These restrictions may include suspension of a product until the FDA is assured that quality standards can be met, continuing oversight of manufacturing by the FDA under a "consent decree," which frequently includes the imposition of costs and continuing inspections over a period of many years, as well as possible withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval, including possible user fees.

The FDA also may require a Boxed Warning (e.g., a specific warning in the label to address a specific risk, sometimes referred to as a "Black Box Warning"), which has marketing restrictions, and post-marketing testing, or Phase 4 testing, as well as a Risk Evaluation and Minimization Strategy (REMS) 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.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are subject to regulation and enforcement by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services ("CMS"), the Department of Health and Human Services Office of Inspector General, the U.S. Federal Trade Commission, the U.S. Department of Justice and individual United States Attorney's offices within the Department of Justice, state attorneys general and state and local governments. To the extent applicable, we must comply with the fraud and abuse provisions of the Social Security Act, the federal Anti-Kickback Statute, the False Claims Act, both federal and state physician sunshine acts, the privacy and security provisions of HIPAA, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the VHCA, each as amended. Certain pricing and rebate provisions of the Inflation Reduction Act of 2022 may require additional pricing disclosure obligations for our products. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Under the Veterans Health Care Act ("VHCA"), drug companies are required to offer certain pharmaceutical products at a reduced price to a number of federal agencies, including the United States Department of Veterans Affairs and United States Department of Defense, the Public Health Service and certain private Public Health Service-designated entities in order to participate in other federal funding programs including Medicare and Medicaid. Legislative changes have purported to require that discounted prices be offered for certain United States Department of Defense purchases for its TRICARE program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations. Furthermore, the Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA presents unique challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. The failure to comply with laws governing international business practices may result in substantial penalties, including civil and criminal penalties.

In order to distribute products commercially, we must comply with federal and state laws and regulations that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors which ship products into the state, even if such manufacturers or distributors have no place of business within the state. Federal and some state laws also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including the use of technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, register their sales representatives, as well as prohibit certain other sales and marketing practices. Additionally, the federal Physician Payments Sunshine Act and implementing regulations promulgated pursuant to Section 6002 of the healthcare reform law requires the tracking and reporting of certain transfers of value made to certain healthcare practitioners and teaching hospitals as well as ownership by a physician or a physician's family member in a pharmaceutical manufacturer. The Sunshine Act requirements were expanded in January 2021 to include physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists & anesthesiologist assistants, and certified nurse-midwives as covered recipients. Finally, all of our activities are potentially subject to federal and state consumer protection and unfair competition laws. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state, and federal authorities.

Europe/Rest of World Government Regulation

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. For example, in the European Union, a clinical trial application ("CTA") must be submitted to each member state's national health authority and 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 from country to country and the time 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 Declaration of Helsinki.

To obtain marketing approval of a drug under European Union regulatory systems, we may submit marketing authorization applications either under a centralized, decentralized or national 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, and optional for those products that are highly innovative or for which a centralized process is in the interest of patients. For our products and product candidates that have received or will receive orphan designation in the European Union, they will qualify for this centralized procedure, under which each product's marketing authorization application will be submitted to the EMA. Under the centralized procedure in the European Union, the maximum time frame for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Scientific Advice Working Party of 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, defined by three cumulative criteria: the seriousness of the disease, such as heavy 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.

The decentralized procedure provides possibility 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. 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. If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points may eventually be referred to the European Commission, whose decision is binding on all member states.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America, Asia and Israel, 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 Declaration of Helsinki.

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.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the coverage and reimbursement decisions made by payors. In the United States, third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product. Payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Several significant laws have been enacted in the United States which affect the pharmaceutical industry and additional federal and state laws have been proposed in recent years. For example, the IRA includes several provisions to lower prescription drug costs for people with Medicare and reduce drug spending by the federal government, including allowing Medicare to negotiate prices for certain prescription drugs, requiring drug manufacturers to pay a rebate to the federal government if prices for single-source drugs and biologicals covered under Medicare Part B and nearly all covered drugs under Part D increase faster than the rate of inflation (CPI-U), and limiting out of pocket spending for Medicare Part D enrollees. Additionally, On October 14, 2022, President Biden signed Executive Order 14087 on "Lowering Prescription Drug Costs for Americans." The Executive Order specifically requests that the Center for Medicare and Medicaid Innovation consider "models that may lead to lower cost sharing for commonly used drugs and support value-based payment that supports high-quality care." The implementation of the IRA, Executive Order 14087, or other legislative or regulatory reform efforts present uncertainty around restrictions that may be imposed on pricing for our products as well as regulatory compliance issues.

Federal, state and local governments in the United States continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs. Future legislation and regulation could further limit payments for pharmaceuticals such as the product candidates that we are developing. In addition, court decisions have the potential to affect coverage and reimbursement for prescription drugs. It is unclear whether future legislation, regulations or court decisions will affect the demand for our product candidates once commercialized.

Different pricing and reimbursement schemes exist in other countries. In the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure of healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any drug candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Intellectual Property

Our success depends, at least in part, on our ability to protect our proprietary technology and intellectual property, and to operate without infringing or violating the proprietary rights of others. We rely on a combination of patent, trademark, trade secret and copyright laws, know-how, intellectual property licenses and other contractual rights (including confidentiality and invention assignment agreements) to protect our intellectual property rights.

Patents

As of December 31, 2023, we owned for use within our field of business 14 patents and patent applications, all of which are granted or pending, respectively, in the United States, most were also filed in Europe, Canada and Israel and some were additionally filed in Russia, Turkey, certain Latin American countries, Australia and other countries, including one PCT applications and three U.S. provisional applications. In addition, we own a patent family protecting pulmonary delivery of Alpha 1 antitrypsin, filed in 2007, in a variety of jurisdictions, including Canada, Germany, France, Italy, Netherlands, Ireland, Belgium, Great Britain, Israel, Russia and Mexico. Furthermore, we own a patent family filed in 2018, protecting our manufacturing process of immunoglobulins. This patent family includes an allowed application in the U.S. and pending applications in Canada, Europe and Israel.

Our patents generally relate to the separation and purification of proteins and their respective pharmaceutical compositions. Our patents and patent applications further relate to the use of our products for a variety of clinical indications, and their delivery methods. Our patent applications further relate to the production of recombinant AAT-1 and uses thereof for clinical indications. Our patent applications further relate to the system and method for purification of immunoglobulins from a biological sample; and to the use of acellular plasma for various indications. Our patents and patent applications are expected to expire at various dates between 2024 and 2043. We also rely on trade secrets to protect certain aspects of our separation and purification technology.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our patent applications or any patent applications that we license will result in the issuance of any patents and there is no guarantee that patent applications that were filed with the patent offices, which are still pending, will be eventually granted and will be registered. Additionally, our issued patents and those that may be issued in the future may be challenged, opposed, narrowed, circumvented or found to be invalid or unenforceable, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. We cannot be certain that we were the first to file the inventions claimed in our owned patents or patent applications. In addition, our competitors or other third parties may independently develop similar technologies that do not fall within the scope of the technology protected under our patents, or duplicate any technology developed by us, and the rights granted under any issued patents may not provide us with any meaningful competitive advantages against these competitors. Furthermore, because of the extensive time required for research and development, testing and regulatory review of a potential product until authorization for marketing, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

Trademarks

We rely on trade names, trademarks and service marks to protect our name brands. Our registered trademarks in several countries, such as United States and the European Union, Israel, and certain Latin American countries, include the trademarks CYTOGAM, GLASSIA, HEPAGAM, HEPAGAM B, KAMRAB, KEDRAB, KAMADA, KAMRHO, KAMRHO-D, KAMRHO-D IM, KR (design mark), REBINOLIN, РЕБИНОЛИН (Rebinolin in Cyrillic), RESPIKAM, KAMADA RESPIRA, VARIZIG, VENTIA, WINRHO and WINRHO SDF.

Trade Secrets and Confidential Information

We rely on, among other things, confidentiality and invention assignment agreements to protect our proprietary know-how and other intellectual property that may not be patentable, or that we believe is best protected by means that do not require public disclosure. For example, we require our employees, consultants and service providers to execute confidentiality agreements in connection with their engagement with us. Under such agreement, they are required, during the term of the commercial relationship with us and thereafter, to disclose and assign to us inventions conceived in connection with their services to us. However, there can be no assurance that these agreements will be fulfilled or shall be enforceable, or that these agreements will provide us with adequate protection. See "Item 3. Key Information — D. Risk Factors — In addition to patented technology, we rely on our unpatented proprietary technology, trade secrets, processes and know-how."

We may be unable to obtain, maintain and protect the intellectual property rights necessary to conduct our business, and may be subject to claims that we infringe or otherwise violate the intellectual property rights of others, which could materially harm our business. For a more comprehensive summary of the risks related to our intellectual property, see "Item 3. Key Information — D. Risk Factors."

Property

Our production plant was built on land that Kamada Assets (2001) Ltd. ("Kamada Assets"), our 74%-owned Israeli subsidiary, leases from the Israel Land Administration pursuant to a capitalized long-term lease. Kamada Assets subleases the property to us. The property originally covered an area of approximately 16,880 square meters. The initial sublease expires in 2058 and we have an option to extend the sublease for an additional term of 49 years. On November 1, 2021, pursuant to a new area outline approved by the Israel Lands Administration, the covered area was reduced to 14,880 square meters. The production plant includes our manufacturing facility, manufacturing support systems, packaging, warehousing and logistics areas and laboratory facilities, as well as office buildings.

In addition, we lease approximately 2,200 square meters of office and laboratory facility at a building located in the Kiryat Weizmann Science Park in Rehovot, Israel. This property houses our corporate office, research and development laboratory and additional departments such as clinical operations, medical, regulatory affairs, compliance, sales and marketing and business development. We sublease approximately 400 square meters of such premises to a third-party lessee. The current lease agreement is in effect until January 2032.

As part of the acquisition of the FDA registered plasma collection center and certain related assets from the privately held B&PR, during 2021, we acquired a 237 square meters facility in Beaumont, TX, which we use as a plasma collection center.

In addition, during 2021, and as part of the establishment of our U.S. commercial operations, we leased office space within a shared office facility in Hoboken, NJ.

On March 7, 2023, our U.S. subsidiary Kamada Plasma LLC entered into a lease agreement for a 12,000 square feet premises in Uvalde, Texas to be used as a plasma collection center. The lease is in effect for an initial period of ten years commencing on the rent commencement date on February 16, 2024. We have the option to extend the lease for two consecutive periods of five years each, upon six months prior written notice. During the fourth quarter of 2023, we initiated the construction of the new plasma collection center in this facility and subject to obtaining the relevant regulatory approvals, we plan to commence plasma collection operations at this new facility in 2024.

Environmental

We believe that our operations comply in material respects with applicable laws and regulations concerning the environment. While it is impossible to predict accurately the future costs associated with environmental compliance and potential remediation activities, compliance with environmental laws is not expected to require significant capital expenditures and has not had, and is not expected to have, a material adverse effect on our earnings or competitive position. For more information see "Item 3. Key Information —D. Risk Factors — Risks Related to Our Operations and Industry – *We are subject to extensive environmental, health and safety, and other laws and regulations.*"

Organizational Structure

Our subsidiaries are set forth below. All subsidiaries are either wholly owned by us or controlled by us. All companies are incorporated and registered in the country in which they operate as listed below:

Legal Name	Jurisdiction
KI Biopharma LLC	Delaware, USA
Kamada Inc.	Delaware, USA
Kamada Plasma LLC	Delaware, USA (wholly owned by Kamada Inc.)
Kamada Assets (2001) Ltd.	Israel
Kamada Ireland Limited	Ireland

Item 4A. Unresolved Staff Comments

Not applicable.

Item 5. Operating and Financial Review and Prospects

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes to those statements included elsewhere in this Annual Report. In addition to historical consolidated financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under "Item 3. Key Information—D. Risk Factors" and elsewhere in this Annual Report.

The audited consolidated financial statements for the years ended December 31, 2023, 2022 and 2021 in this Annual Report have been prepared in accordance with IFRS as issued by the IASB.

Overview

We are a commercial stage global biopharmaceutical company with a portfolio of marketed products indicated for rare and serious conditions and a leader in the specialty plasma-derived field focused on diseases of limited treatment alternatives. We are also advancing an innovative development pipeline targeting areas of significant unmet medical need. Our strategy is focused on driving profitable growth from our significant commercial catalysts as well as our manufacturing and development expertise in the plasma-derived and biopharmaceutical markets.

We operate in two segments: (i) the Proprietary Products segment, which includes our six FDA approved plasma-derived biopharmaceutical products - KEDRAB, CYTOGAM, VARIZIG, WINRHO SDF, HEPGAM B and GLASSIA, as well as KAMRAB, KAMRHO (D) and two types of equine-based anti-snake venom (ASV) products; all of which we market internationally in more than 30 countries. We manufacture our proprietary products at our cGMP compliant FDA-approved production facility located in Beit Kama, Israel, using our proprietary platform technology and know-how for the extraction and purification of proteins and IgGs from human plasma, as well as at third party contract manufacturing facilities; and (ii) the Distribution segment, in which we leverage our expertise and presence in the Israeli market by distributing, for use in Israel, more than 25 pharmaceutical products supplied by international manufacturers and in addition have eleven biosimilar products in our portfolio, which, subject to EMA and IMOH approvals, are expected to be launched in Israel through 2028.

Our Commercial Activities

As part of our Proprietary Products segment, we market KEDRAB, a human rabies immune globulin (HRIG), in the United States through a strategic distribution and supply agreement with Kedrion. Our 2023 revenues from sales of KEDRAB to Kedrion totaled $32.8 million as compared to $16.2 million and $11.9 million during 2022 and 2021, respectively. Such increase represents the increased demand for KEDRAB in the U.S. market in 2023. In December 2023, we entered into a binding memorandum of understanding with Kedrion for the amendment and extension of the distribution agreement between the parties, which represents the largest commercial agreement secured by us to date, according to which (among other things), within the first four years of the eight-year term, which began in January 2024, Kedrion will purchase minimum quantities of KEDRAB with aggregate revenues to us of approximately $180 million. KEDRAB's in-market sales in the United States grew significantly in 2023 as compared to 2022 and are currently expected to continue to grow through the eight-year term. The binding memorandum of understanding includes the potential expansion of KEDRAB distribution by Kedrion to other territories beyond the United States and the parties' agreement to collaborate to expand the distribution of Kedrion's products by us in Israel.

We sell CYTOGAM, a Cytomegalovirus Immune Globulin Intravenous (Human) (CMV-IGIV), indicated for prophylaxis of CMV disease associated with solid organ transplantation in the United States and Canada. Following FDA approval of the CYTOGAM technology transfer process obtained in May 2023, CYTOGAM manufactured at our Israeli facility has been available for commercial sale in the United States since October 2023. Total revenues from sales of CYTOGAM for the years ended December 31, 2023 and 2022 (the first full year during which we sold the product), were $17.2 million and $22.6 million, respectively. While our CYTOGAM sales decreased in 2023, available market information suggests that end-user utilization only marginally decreased between 2023 and 2022. We believe that the reduction in our sales of CYTOGAM in 2023 stemmed from inventory management by wholesalers, minimizing orders for short-dated inventory, with an expiry date of December 2023 or January 2024 (which inventory was acquired by us from Saol as part of the November 2021 acquisition; for details, see "Item 5. Operating and Financial Review and Prospects—Key Components of Our Results of Operations—*Business Combination*"), during the first nine months of the year until new batches of CYTOGAM manufactured at our Israeli facility became available commencing in October 2023. During the fourth quarter of 2023 and through January of 2024, monthly CYTOGAM sales increased as compared to average monthly sales during 2023, as did end user utilization. We believe that our clinical and medical affairs activities, including working with leading U.S-based transplantation experts on the collection and presentation of real-world data evaluating the advantages of CYTOGAM usage will continue to drive awareness of CYTOGAM, which in turn will support continued sales growth.

We believe that sales of KEDRAB and CYTOGAM which combined generated more than 50% of gross profitability in the year ended December 31, 2023, will continue to increase in the coming years and will be a major growth catalyst for the foreseeable future.

We sell VARIZIG, WINRHO SDF and HEPGAM B in the United States, Canada and several other international markets, mainly in South America and the Middle East and North Africa ("MENA") regions. Total revenues from sales of these products for the years ended December 31, 2023, and 2022 (the first full year during which we sold these products), was $26.7 million and $29.5 million, respectively. The decrease in sales of these products between the years is primarily associated with inventory management of our distributors as well as changes in supply schedules under certain tenders, and we expect sales of these products to grow in 2024 as compared to 2023.

We are entitled to royalty income on sales by Takeda of GLASSIA in the United States (as well as in Canada, Australia and New Zealand to the extent GLASSIA will be approved and sales will be generated in these other markets) at a rate of 12% on net sales through August 2025 and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually for each year from 2022 to 2040. During 2021, Takeda obtained a marketing authorization approval for GLASSIA from Health Canada, and it is expected to commence sales of GLASSIA in Canada during 2024, following which we will also be entitled to royalty income at the same rates from such sales. During 2023, we recognized total revenues for royalty income from Takeda of $16.1 million, as compared to $12.2 million during 2022 (which represented royalty income for the period between March and December of 2022). In 2022, we also recognized a $2.0 million one-time payment on account of the transfer, to Takeda, of the GLASSIA U.S. BLA. Based on current GLASSIA sales and forecasted future growth, we expect to receive royalties from Takeda in the range of $10 million to $20 million per year for 2024 to 2040 on GLASSIA sales. Historically, until mid-2021, we generated revenues on sales of GLASSIA, manufactured by us, to Takeda for further distribution in the United States.

We also market GLASSIA in other counties (mainly Russia, Argentina and Israel and in some of these markets under a different brand name) through local distributors. Total revenues derived from sales of GLASSIA in all other countries during 2023 was $7.4 million, as compared to $5.9 million and $7.6 million during 2022 and 2021, respectively. These ex-U.S. market sales of GLASSIA generated more than 40% gross margin in the year ended December 31, 2023. In May 2023, Swissmedic, the national authorization and supervisory authority for drugs and medical products in Switzerland, granted marketing authorization for GLASSIA for AATD in Switzerland. We have partnered with the IDEOGEN Group, a company focused on the commercialization of specialty medicines for rare diseases across Europe, for the commercialization of GLASSIA in Switzerland, and GLASSIA was commercially launched in Switzerland in December 2023, upon obtaining the required reimbursement coverage.

Our 2023 revenues from the sales of the remaining Proprietary products, including KAMRAB (a human rabies immune globulin (HRIG) sold by us outside the U.S. market) and KAMRHO (D) IM (for prophylaxis of hemolytic disease of newborns), as well as our anti-snake venoms sold to the IMoH, totaled $15.2 million, as compared to $13.9 million and $18.4 million during 2022 and 2021, respectively.

We own an FDA licensed plasma collection center that we acquired in March 2021 from the privately held B&PR based in Beaumont, Texas, which originally specialized in the collection of hyper-immune plasma used in the manufacture of KAMRHO (D). In 2023, we significantly expanded our hyper-immune plasma collection in this center by obtaining an FDA approval for the collection of hyper-immune plasma to be used in the manufacture of KAMRAB and KEDRAB, which is plasma that contains high levels of antibodies from donors who have been previously vaccinated by an active rabies vaccine, and started collections of such plasma during 2023. In March 2023, we entered into a lease agreement for a facility in Uvalde, Texas, and subsequently initiated construction activities to establish a new plasma collection center in that facility. We expect to commence plasma collection operations at this new center during 2024, following the completion of its construction and obtaining the required regulatory approvals. The new center is expected to collect normal source plasma to be sold for manufacturing by third parties, as well as hyper-immune specialty plasma required for manufacturing of our proprietary products. During early 2024, we plan to lease a subsequent facility and initiate construction activities to establish our third plasma collection center. We believe that the expansion of our plasma collection capabilities will allow us to better support our hyperimmune plasma needs as well as generate additional revenues through sales of collected normal source plasma.

Our Distribution segment is comprised of sales in Israel of pharmaceutical products manufactured by third parties. Sales generated by our Distribution segment during 2023 totaled $27.1 million, as compared to $26.7 million and $28.1 million during 2022 and 2021, respectively. The majority of the revenues generated in our Distribution segment are from plasma-derived products manufactured by European companies, and its sales represented approximately 76%, 75% and 84% of our Distribution segment revenues for the years ended December 31, 2023, 2022 and 2021, respectively. Over the past several years we continued to extend our Distribution segment products portfolio to non-plasma derived products, including entering into an agreement with Alvotech and two additional companies for the distribution in Israel of eleven different biosimilar products which, subject to EMA and subsequently IMOH approvals, are expected to be launched in Israel through 2028. We believe that sales generated by the launch of the biosimilar products portfolio will become a major growth catalyst. We currently estimate the potential aggregate peak revenues, achievable within several years of launch, generated by the distribution of all eleven biosimilar products to be in the range of approximately $30 million to $34 million annually.

In addition to our commercial operation, we invest in research and development of new product candidates. Our leading investigational product is Inhaled AAT for AATD, for which we are continuing to progress the InnovAATe clinical trial, a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial. We have additional product candidates in early development stage. For additional information regarding our research and development activities, see "— *Our Development Product Pipeline*".

We continue to focus on driving profitable growth through expanding our growth catalysts which include: investment in the commercialization and life cycle management of our commercial Proprietary products, led by KEDRAB and CYTOGAM sales in the U.S. market; continued growth of our Proprietary hyper-immune portfolio's revenues in existing and new geographic markets through registration and launch of the products in new territories; expanding sales of GLASSIA in ex-U.S. markets; generating royalties from GLASSIA sales by Takeda; expanding our plasma collection capabilities in support of our growing demand for hyper-immune plasma as well as sales of normal source plasma to other plasma-derived manufacturers; exploring strategic business development opportunities to identify a potential acquisition or in-licensing targeted product synergistic to our existing commercial activities that could be added to our proprietary products portfolio; continued increase of our Distribution segment revenues specifically through launching the eleven biosimilar products in Israel; and leveraging our FDA-approved IgG platform technology, manufacturing, research and development expertise to advance development and commercialization of additional product candidates, including our investigational Inhaled AAT product, and identify potential commercial partners for this product.

We currently expect to generate total revenues for the fiscal year 2024 in the range of $156 million to $160 million and adjusted EBITDA in the range of $27 million to $30 million. The projected 2024 revenue and adjusted EBITDA forecast represents double digit growth over fiscal year 2023.

Non-IFRS Financial Measures

We present EBITDA and adjusted EBITDA because we use these non-IFRS financial measures to assess our operational performance, for financial and operational decision-making, and as a means to evaluate period-to-period comparisons on a consistent basis. Management believes these non-IFRS financial measures are useful to investors because: (1) they allow for greater transparency with respect to key metrics used by management in its financial and operational decision-making and provide investors with a meaningful perspective on the current underlying performance of the Company's core ongoing operations; and (2) they exclude the impact of certain items that are not directly attributable to our core operating performance and that may obscure trends in the core operating performance of the business. Non-IFRS financial measures have limitations as an analytical tool and should not be considered in isolation from, or as a substitute for, our IFRS results. We expect to continue reporting non-IFRS financial measures, adjusting for the items described below, and we expect to continue to incur expenses similar to certain of the non-cash, non-IFRS adjustments described below. Accordingly, unless otherwise stated, the exclusion of these and other similar items in the presentation of non-IFRS financial measures should not be construed as an inference that these items are unusual, infrequent or non-recurring. EBITDA and adjusted EBITDA are not recognized terms under IFRS and do not purport to be an alternative to IFRS terms as an indicator of operating performance or any other IFRS measure. Moreover, because not all companies use identical measures and calculations, the presentation of EBITDA and adjusted EBITDA may not be comparable to other similarly titled measures of other companies. EBITDA and adjusted EBITDA are defined as net income (loss), plus income tax expense, plus or minus financial income or expenses, net, plus or minus income or expense in respect of securities measured at fair value, net, plus or minus income or expenses in respect of currency exchange differences and derivatives instruments, net, plus depreciation and amortization expense, plus non-cash share-based compensation expenses and certain other costs.

For the projected 2024 adjusted EBITDA, the company is unable to provide a reconciliation of this forward measure to the most comparable IFRS financial measure because the information for these measures is dependent on future events, many of which are outside of our control. Additionally, estimating such forward-looking measures and providing a meaningful reconciliation consistent with our accounting policies for future periods is meaningfully difficult and requires a level of precision that is unavailable for these future periods and cannot be accomplished without unreasonable effort. Forward-looking non-IFRS measures are estimated in a manner consistent with the relevant definitions and assumptions noted in the company's non-IFRS measures for historical periods.

Key Components of Our Results of Operations

Business Combination

In November 2021, we acquired a portfolio of the following four FDA approved plasma-derived hyperimmune commercial products from Saol: CYTOGAM, HEPAGAM B, VARIZIG and WINRHO SDF. Under the terms of the agreement, we paid Saol a $95.0 million upfront payment, and agreed to pay up to an additional $50.0 million of contingent consideration subject to the achievement of sales thresholds for the period commencing on the acquisition date and ending on December 31, 2034. The first and second sales threshold were achieved by the end of 2022 and 2023, respectively. The $3.0 million contingent consideration payment on account of the first sales threshold was paid during 2023. The second sales threshold was met, and the second $3.0 million milestone payment was paid during February 2024. Subject to certain conditions defined in the agreement between the parties, we may be entitled for up to a $3.0 million credit deductible from the contingent consideration payments due for the years 2023 through 2027. During 2023, the entitlement for the credit was not met. In addition, we acquired inventory valued at $14.4 million and agreed to pay the consideration to Saol in ten quarterly installments of $1.5 million each or the remaining balance at the final installment, of which through the end of 2023 we paid all but the last two installments which will be paid during the first half of 2024.

The acquisition was categorized as a business combination and accounted for by applying the acquisition method, pursuant to which we identified and valued the acquired assets and assumed liabilities. The excess amount of the acquisition cost over the net value of the acquired assets and assumed liabilities is recorded as goodwill. The following acquired assets and intangible assets, and their respective fair value as of the acquisition date were identified: Inventory $22.8 million; Customer Relations $33.5 million; Intellectual Property $79.1 million; and Assumed Contract Manufacturing Agreement $8.5 million. Intangible assets with a finite useful life are amortized on a straight-line basis over their useful life (estimated 6-20 years). During each of the years ended December 31, 2023 and 2022, we accounted for $7.1 of amortization expenses associated with such intangible assets. Intangible assets and goodwill are reviewed for impairment whenever there is an indication that the asset may be impaired.

In addition to accounting for the contingent consideration and deferred inventory related instalment payments described above, we assumed certain of Saol's liabilities for the future payment of royalties (some of which are perpetual) and milestone payments to third parties subject to the achievement of corresponding CYTOGAM related net sales thresholds and milestones. The fair value of such assumed liabilities at the acquisition date was estimated at $47.2 million. Such assumed liabilities include:

- Royalties: 10% of the annual global net sales of CYTOGAM up to $25.0 million and 5% of net sales that are greater than $25.0 million, in perpetuity; 2% of the annual global net sales of CYTOGAM in perpetuity; and 8% of the annual global net sales of CYTOGAM for period of six years following the completion of the technology transfer of the manufacturing of CYTOGAM to us, subject to a maximum aggregate of $5.0 million per year and for total amount of $30.0 million throughout the entire six years period.
- Sales milestones: $1.5 million in the event that the annual net sales of CYTOGAM in the U.S. market exceeds $18.8 million during the twelve months period ended June 30, 2022, which milestone was met and the milestone payment was paid during 2023; and, $1.5 million in the event that the annual net sales of CYTOGAM in the U.S. market exceeds $18.4 million during the twelve months period ended June 30, 2023, which milestone was not met and the milestone payment was therefore not required to be paid.

- Milestone: $8.5 million upon the receipt of FDA approval for the manufacturing of CYTOGAM at the Company's manufacturing facility in Israel, which milestone was met and the milestone payment was paid during 2023.

During each of the years ended December 31, 2023, and 2022, we accounted for revaluation of such contingent consideration and assumed liabilities in an amount of $1.0 million and $6.3 million respectively, and such costs were recorded as part of the financial expenses, net.

Revenues

In our Proprietary Products segment, we generate revenues from the sale of products to wholesalers in the U.S. market, strategic partners (specifically KEDRAB to Kedrion), local distributors in ex-U.S. markets, HMOs and local hospitals**.** Revenues from our Proprietary Products segments also include royalty income from strategic partners (specifically royalties paid by Takeda on account of their sales of GLASSIA). In our Distribution segment, we generate revenues from the sale in Israel of imported products produced by third parties. Revenues are presented net of any discounts, chargebacks, fees, dues and/or marketing contribution payments extended to our partners, distributors or end users of our products.

We derived approximately 52%, 50% and 48% of our total revenues for the years ended December 31, 2023, 2022 and 2021, respectively, from sales in the United States, approximately 22%, 25% and 35% of our total revenues for the years ended December 31, 2023, 2022 and 2021, respectively, from sales in Israel (including both sales for our Proprietary Products segment and Distribution segment), approximately 9%, 9% and 9% of our total revenues for the years ended December 31, 2023, 2022 and 2021, respectively, from sales in Latin America, approximately 8%, 8% and 0% of our total revenues for the years ended December 31, 2023, 2022 and 2021, respectively, from sales in Canada , approximately 5%, 4% and 5% of our total revenues for the years ended December 31, 2023, 2022 and 2021, respectively, from sales in Europe, and approximately 4%, 4% and 3% of our total revenues for the years ended December 31, 2023, 2022 and 2021, respectively, from sales in Asia (excluding Israel).

Cost of Revenues

Cost of revenues in our Proprietary Products segment includes expenses related to the manufacturing of products such as raw materials (including plasma), payroll (including bonus, equity-based compensation, and other benefits), utilities, laboratory costs and depreciation. In addition, part of the cost of revenues derived from payment on account of manufacturing services provided by third parties. Cost of revenues also includes provisions for the costs associated with manufacturing scraps and inventory write-offs.

Cost of revenues includes amortization expenses related to intangible assets recognized pursuant to the acquisition of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF. Intangible assets which amortization is accounted for in the costs of revenues include the acquired products intellectual property and an assumed contract manufacturing agreement.

A significant portion of our manufacturing costs are for raw materials consisting of plasma or plasma fraction. In order to ensure the availability of plasma and plasma fraction, we secured supply agreements with multiple suppliers, including Kedrion for the manufacturing of KEDRAB and KAMRAB, CSL Behring for the manufacturing of CYTOGAM and Takeda for the manufacturing of GLASSIA. We intend to secure long term plasma supply agreements with other suppliers to support manufacturing needs for CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF, and we plan to leverage our plasma collection experience to expand our plasma collection capacity and to open additional plasma collection centers in the United States to support our continued plasma needs and reduce our dependency on third party plasma suppliers.

Costs of revenues in our Distribution segment consists of costs of products acquired, packaging and labeling for sales by us in Israel.

Gross Profit

Gross profit is the difference between total revenues and the cost of revenues. Overall gross profit is mainly affected by volume and mix of sales, as well as manufacturing efficiencies, cost of raw materials and plant maintenance and overhead costs.

Our gross margins in our Proprietary Products segment, which were 45%, 43% and 36% for the years ended December 31, 2023, 2022 and 2021, respectively, are generally higher than in our Distribution segment, which were 12%, 9% and 11% for the years ended December 31, 2023, 2022 and 2021, respectively.

The increase in gross profitability in our Proprietary Products segment during the year ended December 31, 2023, was mainly due to the significant increase in sales of KEDRAB to Kedrion which significantly improved our product sales mix in this segment. The increase in gross profitability in our Proprietary Products segment during the year ended December 31, 2022, was mainly as a result of a positive product sales mix, led by sales of KEDRAB and CYOTGAM in the U.S. market and GLASSIA royalties.

Research and Development Expenses

The development of pharmaceutical products, including plasma-derived protein therapeutics, is characterized by significant up-front product development costs. Research and development expenses are incurred for the development of new products and newly revised processes for existing products and includes expenses for pre-clinical and clinical trials, development activities in the different fields, the advanced understanding of the mechanism of action of our products, improving existing products and processes, development work at the request of regulatory authorities and strategic partners, as well as communication with regulatory authorities related to our commercial products and clinical programs. In addition, such expenses include development materials, payroll for research and development personnel (including payroll, bonus, equity-based compensation and other benefits), including scientists and professionals for product registration and approval, external advisors, and the allotted cost of our manufacturing facility for research and development purposes. While research and development expenses are unallocated on a segment basis, the activities generally relate to our existing or in development proprietary products.

Product development costs may fluctuate from period to period, as our product candidates proceed through various stages of development. We expect to continue to incur research and development expenses related to clinical trials, as well as other ongoing, planned, or future clinical trials with regard to our product pipeline. See "Item 4. Information on the Company — Our Development Product Pipeline."

To reduce costs related to the development and regulatory approval of new protein therapeutics, in some cases we seek to share development costs with strategic partners, such as Takeda for the required post marketing clinical trials for GLASSIA in the United States, Kedrion for the clinical trials for KEDRAB in the United States required for product approval and post marketing commitments. See "Item 4. Information on the Company — Strategic Partnerships." In addition, we seek grants from dedicated governmental funds for partial funding for development projects.

Selling and Marketing Expenses

Selling and marketing expenses principally consist of compensation for employees and executives in sales and marketing related positions (including payroll, bonus, equity-based compensation and other benefits), expenditures incurred for sales incentive, advertising, marketing or promotional activities, shipping and handling costs, 3PL services fees product liability insurance and business development activities, as well as marketing authorization fees to regulatory agencies, including the FDA.

Selling and marketing expenses include amortization expenses related to intangible assets recognized pursuant to the acquisition of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF. Such intangible assets include customer relations.

General and Administrative Expenses

General and administrative expenses consist of compensation for employees in executive and administrative functions (including payroll, bonus, equity compensation and other benefits), office expenses, professional consulting services, public company related costs, directors' and officer's liability insurance and other insurance costs, legal, audit fees, other professional services as well as employee welfare costs.

Financial Income

Financial income is comprised of interest income on amounts invested in bank deposits.

Income (expense) in respect of currency exchange differences and derivatives instruments, net

Income (expense) in respect of currency exchange differences and derivatives instruments, net is comprised of changes in balances denominated in currencies other than our functional currency. Changes in the fair value of derivatives instruments not designated as hedging instruments are reported to profit or loss.

Financial income (expense) in respect of contingent consideration and other long- term liabilities

Financial income (expense) in respect of contingent consideration and other long-term liabilities is comprised of the changes in the balances of the contingent consideration and other long-term liabilities which were accounted for as part of the acquisition of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF (for details, see above under "Key Components of Our Results of Operations—*Business Combination*").

Financial Expenses

Financial expenses are comprised of bank charges, changes in the time value of provisions, the portion of changes in the fair value of financial assets or liabilities at fair value through other comprehensive income and interest and amortization of bank loans and leases.

Taxes on Income

Since our inception we accrued NOLs for tax purposes and as result, have not been required to pay income taxes other than tax withheld in a foreign jurisdiction in 2012 and 2016 and a $1.3 million payment to the Israel Tax Authority in 2016 as a settlement agreement for the tax years 2004-2006. During the year ended December 31, 2018, we accounted for a deferred tax asset on account of a portion of the loss carryforwards for tax purposes that we estimated that we would realize in the following years, and during the years ended December 31, 2020 and 2019, due to the utilization of such loss carryforwards, we recognized tax expenses for the entire amount of such deferred tax asset**.** For the years ended December 31, 2023, 2022 and 2021, we did not account for deferred tax assets nor deferred tax income/expenses.

As of December 31, 2023, we have NOLs for tax purposes of approximately $26.9 million. The NOLs have no expiration date. Following the full utilization of our NOLs, we expect that our effective income tax rate in Israel will reflect the tax benefits discussed below.

Our Israeli based manufacturing facility was granted Approved Enterprise status pursuant to the Investment Law, which made us eligible for a grant and certain tax benefits under that law for a certain investment program. The investment program provided us with a grant in the amount of 24% of our approved investments, in addition to certain tax benefits, which applied to the turnover resulting from the operation of such investment program, for a period of up to ten consecutive years from the first year in which we generated taxable income. The tax benefits under the Approved Enterprise status expired at the end of 2017. Additionally, we obtained a tax ruling from the Israel Tax Authority according to which, among other things, our activity has been qualified as an "industrial activity," as defined in the Investment Law, and was also eligible for tax benefits as a Privileged Enterprise, which applied to the turnover attributed to such enterprise, for a period of up to ten years from the first year in which we generated taxable income. The tax benefits under the Privileged Enterprise status expired at the end of 2023. As of the date of this Annual Report, we have not utilized any tax benefits under the Investment Law, other than the receipt of grants attributable to our Approved Enterprise status. We have applied for a new tax ruling from the Israel Tax Authority according to which, if approved, among other things, our activity would be qualified as an "industrial activity," as defined in Investment Law, and we may be eligible for tax benefits according to the Investment Law, and our income from sales of our proprietary products (including royalties-based income) would be deemed "Preferred Technology Income" and "Preferred income" (within the meaning of the Investment Law). See *"*Item 10. Additional Information — *E. Taxation — Israeli Tax Considerations and Government Programs."*

We may be subject to withholding taxes for payments we receive from foreign countries. If certain conditions are met, these taxes may be credited against future tax liabilities under tax treaties and Israeli tax laws. However, due to our net operating loss carryforward, it is uncertain whether we will be able to receive such credit and therefore, we may incur tax expenses.

As we further expand our sales into other countries, we could become subject to taxation based on such country's statutory rates and our effective tax rate could fluctuate accordingly.

During the year ended December 31, 2021, following the acquisition of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF and the acquisition of the plasma collection center in Beaumont, TX, we initiated commercial operations in the U.S. through our subsidiaries Kamada Inc. and Kamada Plasma LLC. The two entities are subject to U.S. federal and certain state income taxes and file a combined tax return. Income tax expenses due in connection which such activities are included as part of taxes on income in our consolidated statement of operations.

Results of Operations

The following table sets forth certain statement of operations data:

	Year Ended December 31,		
	2023	**2022**	**2021**
	(U.S. Dollars in thousands)		
Revenues from Proprietary Products segment	$ 115,458	$ 102,598	$ 75,521
Revenues from Distribution segment	27,061	26,741	28,121
Total revenues	142,519	129,339	103,642
Cost of revenues from Proprietary Products segment	63,342	58,229	48,194
Cost of revenues from Distribution segment	23,687	24,407	25,120
Total cost of revenues	87,029	82,636	73,314
Gross profit	55,490	46,703	30,328
Research and development expenses	13,933	13,172	11,357
Selling and marketing expenses	16,193	15,284	6,278
General and administrative expenses	14,381	12,803	12,636
Other expense	919	912	753
Operating income (loss)	10,064	4,532	(696)
Financial income	588	91	295
Income (expense) in respect of currency exchange differences and derivatives instruments, net	55	298	(207)
Financial income (expense) in respect of contingent consideration and other long- term liabilities	(980)	(6,266)	(994)
Financial expenses	(1,298)	(914)	(283)
Income (loss) before taxes on income	8,429	(2,259)	(1,885)
Taxes on income	145	62	345
Net income (loss)	$ 8,284	$ (2,321)	$ (2,230)

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

Segment Results

	2023	2022	Change 2023 vs. 2022 Amount	Percent
	(U.S. Dollars in thousands)			
Revenues:				
Proprietary Products	$ 115,458	$ 102,598	$ 12,860	12.5%
Distribution	27,061	26,741	320	1.2%
Total	142,519	129,339	13,180	10.2%
Cost of Revenues:				
Proprietary Products	63,342	58,229	5,113	8.8%
Distribution	23,687	24,407	(720)	(2.9)%
Total	87,029	82,636	4,393	5.3%
Gross Profit:				
Proprietary Products	$ 52,116	$ 44,369	$ 7,747	17.5%
Distribution	3,374	2,334	1,040	44.6%
Total	$ 55,490	$ 46,703	$ 8,787	18.8%

Revenues

For the year ended December 31, 2023, we generated $142.5 million of total revenues, as compared to $129.3 million for the year ended December 31, 2022, an increase of $13.2 million, or approximately 10.2% primarily due to an increase in revenues in the Proprietary Products segment.

The increase in revenues in the Proprietary Products segment in 2023 was primarily due to increased sales of KEDRAB to Kedrion due to increased market share and demand for the product in the U.S. market. KEDRAB sales to Kedrion for the year ended December 31, 2023, totaled $32.8 million, a $16.5 million increase compared to the year ended December 31, 2022. In addition, for the year ended December 31, 2023, we accounted for $16.1 of sales-based royalty income from Takeda, a $3.9 million increase compared to the year ended December 31, 2022. Such increases were offset in part by a decrease of $8.2 million in the combined revenues generated by sales of CYTOGAM, VARIZIG, WINRHO SDF and HEPGAM B, which totaled $43.9 million for the year ended December 31, 2023. While our CYTOGAM sales decreased in 2023, available market information suggests that end-user utilization only marginally decreased between 2023 and 2022. We believe that the reduction in our sales of CYTOGAM in 2023 stemmed from inventory management by wholesalers, minimizing orders for short-dated inventory, with an expiry date of December 2023 or January 2024 (which inventory was acquired by us from Saol as part of the November 2021 acquisition), during the first nine months of the year until new batches of CYTOGAM manufactured at our Israeli facility became available commencing in October 2023. During the fourth quarter of 2023 and through January of 2024, monthly CYTOGAM sales increased as compared to average monthly sales during 2023, as did end user utilization. The decrease in sales of VARIZIG, WINRHO SDF and HEPGAM B in 2023 is primarily associated with inventory management of our distributors as well as changes in supply schedules under certain tenders, and we expect sales of these products to grow in 2024 as compared to 2023.

The increase in revenues in the Distribution segment was primarily in 2023 related to higher demand for certain products in our portfolio.

Cost of Revenues

For the year ended December 31, 2023, we incurred $87.0 million of cost of revenues, as compared to $82.6 million for the year ended December 31, 2022, an increase of $4.4 million, or approximately 5.3%. The increase in costs of revenues is mainly attributable to increased sales. For the year ended December 31, 2023, cost of revenues included $5.4 million of intangible assets amortization costs.

Gross Profit

Gross profit and gross margins in our Proprietary Products segment for the year ended December 31, 2023, were $52.1 and 45.1%, respectively, as compared to $44.4 and 43.2% for the year ended December 31, 2022, respectively, representing an increase of $7.7 million and 17.5%, respectively. Such increase is primarily attributed to the increase in KEDRAB sales to Kedrion due to increased market share and demand for the product in the U.S. market as well as improved product sales mix.

Gross profit and gross margins in our Distribution segment for the year ended December 31, 2023, were $3.4 and 12%, respectively, as compared to $2.3 and 8.7% for the year ended December 31, 2022, respectively, representing an increase of $1.1 million and 44.6%, respectively. Such increase is primarily related to improved product sales mix.

Research and Development Expenses

For the year ended December 31, 2023, we incurred $13.9 million of research and development expenses, as compared to $13.2 million in the year ended December 31, 2022, an increase of $0.7 million, or approximately 6%. The increase was primarily due to increased costs associated with advancing the ongoing pivotal Phase 3 InnovAATe trial for Inhaled AAT as well as our early-stage development programs.

Research and development expenses accounted for approximately 9.8% and 10.2% of total revenues for the years ended December 31, 2023 and 2022, respectively.

Set forth below are the research and development expenses associated with our major development programs in the years ended December 31, 2023 and 2022:

	Year ended December 31,	
	2023	2022
Inhaled AAT	$ 6,055	$ 4,986
Anti-SARS-CoV-2	-	32
Recombinant AAT	-	257
Other early stage development programs	191	61
Unallocated salary	5,110	5,608
Unallocated facility cost allocated to research and development	1,529	1,380
Unallocated other expenses	1,048	909
Total research and development expenses	$ 13,933	$ 13,172

For the years ended December 31, 2023 and 2022, we incurred $5.1 million and $5.6 million, respectively, of unallocated salary expenses which represent all research and development salary expenses, $1.5 million and $1.4 million, respectively, of facility costs allocated to research and development and $1.0 million and $0.9 million, respectively, of unallocated other expenses.

Our current intentions with respect to our major development programs are described in "Business — Our Development Product Pipeline". We cannot determine with full certainty the duration and completion costs of the current or future clinical trials of our major development programs or if, when, or to what extent we will generate revenues from the commercialization and sale of any product candidates. We or our strategic partners may never succeed in achieving marketing approval for any product candidates. The duration, costs and timing of clinical trials and our major development programs will depend on a variety of factors, including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rates and significant and changing government regulation and whether our current or future strategic partners are committed to and make progress in programs licensed to them, if any. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. See "Item 3. Key Information — D. Risk Factors — Risks Related to Development, Regulatory Approval and Commercialization of Product Candidates."

We will determine which programs to pursue and how much to fund each program in response to the scientific, pre-clinical and clinical outcome and results of each product candidate, as well as an assessment of each product candidate's commercial potential. We cannot forecast with any degree of certainty which of our product candidates, if any, will be subject to future collaborations or how such arrangements would affect our development plans or capital requirements.

Selling and Marketing Expenses

For the year ended December 31, 2023, we incurred $16.2 million of selling and marketing expenses, as compared to $15.3 million for the year ended December 31, 2022, an increase of $0.9 million, or approximately 6%. This increase was primarily due costs associated with our U.S. commercial operations through our wholly owned subsidiary, Kamada Inc. which is responsible for the marketing, sale, and distribution of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF.

Selling and marketing expenses for the years ended December 31, 2023 and 2022 include $1.7 of amortization expenses, respectively, related to intangible assets recognized pursuant to a business combination.

Selling and marketing expenses accounted for approximately 11.4% and 11.8% of total revenues for the years ended December 31, 2023 and 2022, respectively.

General and Administrative Expenses

For the year ended December 31, 2023, we incurred $14.4 million of general and administrative expenses, as compared to $12.8 million for the year ended December 31, 2022, an increase of $1.6 million, or approximately 12.3%. This increase was primarily due to increased administrative, information technology and professional services costs in continued supported of the increased commercial operation.

General and administrative expenses accounted for approximately 10.1% and 9.9% of total revenues for the years ended December 31, 2023 and 2022, respectively.

Other expenses

For the years ended December 31, 2023 and 2022, we incurred $0.9 and $0.9 million of other expenses. For the year ended December 31, 2023, such expenses included costs associated with a planned workforce downsizing at our manufacturing plant in Israel, optimizing staff level to our capacity needs. For the years ended December 31, 2023 and 2022, such expenses also include partial recognition of a milestone payment to be paid to CSL Behring upon completion of the technology transfer of CYTOGAM manufacturing to our manufacturing facility at Beit-Kama, Israel. The milestone payment in the total amount of $8.5 million was paid in full as a lump sum during the third quarter of 2023.

Financial Income

For the years ended December 31, 2023 and 2022, we generated $0.6 and $0.1 million of financial income, respectively. Financial income is primarily comprised of interest income on bank deposits.

Income (expense) in respect of currency exchange differences and derivatives instruments, net

For the year ended December 31, 2023, we generated $0.1 million of income in respect of currency exchange differences on balances in other currencies, mainly the NIS and the Euro versus the U.S. dollar, and derivatives impact, as compared to $0.3 million for the year ended December 31, 2022.

Financial Income (expense) in respect of contingent consideration and other long- term liabilities

For the years ended December 31, 2023 and 2022, we incurred $1.0 million and $6.3 million of financial expense in respect of contingent consideration and other long- term liabilities, respectively. These expenses are in respect of reevaluation of contingent consideration and other long- term liabilities associated with the acquisition of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF (for details regarding the description of such contingent consideration and other long-terms liabilities, see above under "Key Components of Our Results of Operations—*Business Combination*" and for details regarding the payments made on account of these liabilities see below under "Liquidity and Capital Resources").

Financial Expenses

For the year ended December 31, 2023, we incurred $1.3 million of financial expenses, as compared to $0.9 million for the year ended December 31, 2022. Financial expenses in the years ended December 31, 2023 and 2022, were primarily related to interest costs on a debt facility obtained to partially fund the acquisition of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF, as well as outstanding lease obligations. The debt facility was repaid in full during the third quarter of 2023. See below "Liquidity and Capital Resources."

Taxes on Income

For the year ended December 31, 2023, we recorded a $0.2 million tax expense primarily related to our U.S. operations, as compared to a $0.1 million tax expense for the year ended December 31, 2022. Taxes on income for the years ended December 31, 2023 and 2022, were primarily related to our U.S. operations.

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

Segment Results

			Change 2022 vs. 2021	
	2022	2021	Amount	Percent
	(U.S. Dollars in thousands)			
Revenues:				
Proprietary Products	$ 102,598	$ 75,521	$ 27,077	35.9%
Distribution	26,741	28,121	(1,380)	(4.9)%
Total	129,339	103,642	25,697	24.8%
Cost of Revenues:				
Proprietary Products	58,229	48,194	10,035	20.8%
Distribution	24,407	25,120	(713)	(2.8)%
Total	82,636	73,314	9,322	12.7%
Gross Profit:				
Proprietary Products	$ 44,369	$ 27,327	$ 17,042	62.4%
Distribution	2,334	3,001	(667)	(22.2)%
Total	$ 46,703	$ 30,328	$ 16,375	54.0%

Revenues

For the year ended December 31, 2022, we generated $129.3 million of total revenues, as compared to $103.6 million for the year ended December 31, 2021, an increase of $25.7 million, or approximately 24.8%. This increase was primarily due to sales from the portfolio of four acquired FDA-approved IgG products that contributed $52.1 million. During the year ended December 31, 2021, this portfolio generated total sales of $41.9 million, of which we recognized only $5.4 million which were the sales from the acquisition date of November 22, 2021, and December 31, 2021. In addition, KEDRAB sales to Kedrion for the year ended December 31, 2022, totaled $16.2 million, a $4.3 million increase compared to the year ended December 31, 2021, which increase was a result of Kedrion's U.S. in-market sales returning to the pre-COVID-19 pandemic sales. Lastly, for the year ended December 31, 2022, we accounted for revenues of $14.2 million from Takeda, of which $12.2 of sales-based royalty income (for the period between March and December of 2022) and a $2.0 million one-time payment on account of the transfer, to Takeda, of the GLASSIA U.S. BLA. During the year ended December 31, 2021, we generated $26.2 million of sales of GLASSIA to Takeda, which were our last sales of the product to Takeda prior to the completion of transition of its manufacturing to Takeda.

The decrease in revenues in the Distribution segment is primarily related to the reduction of IVIG sales.

Cost of Revenues

For the year ended December 31, 2022, we incurred $82.6 million of cost of revenues, as compared to $73.3 million for the year ended December 31, 2021, an increase of $9.3 million, or approximately 12.7%. The increase in costs of revenues is mainly attributable to increased sales. For the year ended December 31, 2022, cost of revenues included $5.4 million of intangible assets amortization costs and a $4.3 million loss related to a labor strike at our manufacturing plant at Beit-Kama, Israel which was concluded in July 2022.

Gross Profit

Gross profit and gross margins in our Proprietary Products segment for the year ended December 31, 2022, were $44.4 and 43.2%, respectively, as compared to $27.3 and 36.2% for the year ended December 31, 2020, respectively, representing an increase of $17.0 million and 62%, respectively. Such increase is primarily attributed to the sales generated by the portfolio of four acquired FDA-approved IgG products, the increase in KEDRAB sales to Kedrion as well as the royalty income from Takeda on account of their GLASSIA sales.

Gross profit and gross margins in our Distribution segment for the year ended December 31, 2022 were $2.3 and 8.7%, respectively, as compared to $3.0 and 10.7% for the year ended December 31, 2021, respectively, representing a decrease of $0.7 million and 22%, respectively. Such decrease is primarily related to the overall decrease in sales generated in this segment which were driven by reduction of IVIG sales.

Research and Development Expenses

For the year ended December 31, 2022, we incurred $13.2 million of research and development expenses, as compared to $11.4 million in the year ended December 31, 2021, an increase of $1.8 million, or approximately 16.0%. The increase was primarily due to increased costs associated with opening of new clinical sites and accelerating recruitment for the ongoing pivotal Phase 3 clinical trial of Inhaled AAT.

Research and development expenses accounted for approximately 10.2% and 11.0% of total revenues for the years ended December 31, 2022 and 2021, respectively.

Set forth below are the research and development expenses associated with our major development programs in the years ended December 31, 2022 and 2021:

	Year ended December 31,	
	2022	**2021**
Inhaled AAT	$ 4,986	$ 2,562
Anti-SARS-CoV-2	32	180
Recombinant AAT	257	528
Other early stage development programs	61	-
Unallocated salary	5,608	5,076
Unallocated facility cost allocated to research and development	1,380	2,138
Unallocated other expenses	909	873
Total research and development expenses	$ 13,172	$ 11,357

For the years ended December 31, 2022 and 2021, we incurred $5.6 million and $5.1 million, respectively, of unallocated salary expenses which represent all research and development salary expenses, $1.4 million and $2.1 million, respectively, of facility costs allocated to research and development and $0.9 million and $0.9 million, respectively, of unallocated other expenses.

Selling and Marketing Expenses

For the year ended December 31, 2022, we incurred $15.3 million of selling and marketing expenses, as compared to $6.3 million for the year ended December 31, 2021, an increase of $9.0 million, or approximately 143.5%. This increase was primarily due to the establishment of our U.S. commercial operations through our wholly owned subsidiary, Kamada Inc. which is responsible for the marketing, sale, and distribution of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF.

In addition, the increase in selling and marketing expenses is attributable to amortization expenses related to intangible assets recognized pursuant to a business combination, which for the years ended December 31, 2022 and 2021, amounted to $1.7 million and $0.2 million, respectively.

Selling and marketing expenses accounted for approximately 11.8 % and 6.1% of total revenues for the years ended December 31, 2022 and 2021, respectively.

General and Administrative Expenses

For the year ended December 31, 2022, we incurred $12.8 million of general and administrative expenses, as compared to $12.6 million for the year ended December 31, 2021, an increase of $0.2 million, or approximately 1.3%. This increase was primarily due to increased costs in support of our U.S. commercial operation.

General and administrative expenses accounted for approximately 9.9% and 12.2% of total revenues for the years ended December 31, 2022 and 2021, respectively.

Other expenses

For the years ended December 31, 2022 and 2021, we incurred $0.9 and $0.8 million of other expenses. For the year ended December 31, 2022, such expenses included partial recognition of an expected milestone payment to be paid to CSL Behring upon completion of the technology transfer of CYTOGAM manufacturing to our manufacturing facility at Beit-Kama, Israel. For the year ended December 31, 2021, such expenses included a one-time expense of $0.7 million related to excess severance remuneration for employees who were laid-off as part of a planned workforce downsizing undergone in connection with the transition of GLASSIA manufacturing to Takeda.

Financial Income

For the years ended December 31, 2022 and 2021, we generated $0.1 and $0.3 million of financial income, respectively. Financial income is primarily comprised of interest income on bank deposits and to a limited extent short-term investments.

Income (expense) in respect of currency exchange differences and derivatives instruments, net

For the year ended December 31, 2022, we generated $0.3 million of income in respect of currency exchange differences on balances in other currencies, mainly the NIS and the Euro versus the U.S. dollar, and derivatives impact, as compared to incurring $0.2 million of expenses in respect to currency exchange differences and derivatives instruments for the year ended December 31, 2021.

Financial Income (expense) in respect of contingent consideration and other long- term liabilities

For the year ended December 31, 2022, we incurred $6.3 million of expenses, as compared to $1.0 million for the year ended December 31, 2021. These expenses are in respect of reevaluation of contingent consideration and other long- term liabilities associated with the acquisition of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF.

Financial Expenses

For the year ended December 31, 2022, we incurred $0.9 million of financial expenses, as compared to $0.3 million for the year ended December 31, 2021. Financial expenses in the years ended December 31, 2022 and 2021, was primarily related to interest costs on debt facility obtained to partially fund the acquisition of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF. See below "Liquidity and Capital Resources."

Taxes on Income

For the year ended December 31, 2022, we recorded a $0.1 million tax expense primarily related to our U.S. operations. For the year ended December 31, 2021, we recorded a $0.3 million tax expense primarily related to excess costs tax payment due to the Israel Tax Authority and current taxes on account of our U.S commercial operations.

Liquidity and Capital Resources

Our primary uses of cash are to fund working capital requirements, research and development expenses and capital expenditures, as well as for acquisitions of new products, product candidates and assets. Historically, we have funded our operations primarily through cash flow from operations (including sales of our proprietary products and distribution products), payments received in connection with strategic partnerships (including milestone payments from collaboration agreements), issuances of ordinary shares (including our 2005 initial public offering and listing on the TASE, our 2013 initial public offering in the United States and listing on Nasdaq, our 2017 underwritten public offering and our 2020 and 2023 private placements), and the issuance of convertible debentures and warrants to purchase our ordinary shares as well as through commercial debt financing for the funding of certain acquisitions.

In September 2023, we consummated a $60 million private placement of approximately 12.6 million ordinary shares to FIMI Opportunity Funds at a price of $4.75 per share, following which its holdings increased to approximately 38% of our outstanding ordinary shares and FIMI Opportunity Funds became our controlling shareholder, within the meaning of the Israeli Companies Law, 1999 (the "Israeli Companies Law"). We used a portion of the proceeds from the private placement to repay the credit facility and loan we secured in connection with the acquisition of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF from Saol in November 2021 (see below "Credit Facility and Loan Agreement with Bank Hapoalim B.M."

The balance of cash and cash equivalents as of December 31, 2023, 2022 and 2021, totaled $55.6 million, $34.3 million and $18.6 million, respectively. We plan to fund our future operations and strategic initiatives (See "Item 4. Information on the Company") through our financial resources, cash generated through our operational activities, which generated $4.3 million during the year ended December 31, 2023, commercialization and or out-licensing of our pipeline product candidates, and to the extent required, raising additional capital through the issuance of equity or debt.

Our capital expenditures for the years ended December 31, 2023, 2022 and 2021 were $5.8 million, $3.8 million and $3.7 million, respectively. Our capital expenditure relates primarily to the maintenance and improvements of our facilities and the construction of new plasma collection centers. We expect our capital expenditures to increase in the coming years mainly due to the planned expansion of our plasma collection operations as well as potentially to facilitate the transition of manufacturing of HEPGAM B, VARIZIG and WINRHO SDF to our manufacturing facility in Beit Kama, Israel, which will require possible upgrades to plant infrastructure as well as to upgrade manufacturing automation. To date, we have not made any material commitments towards such planned expenditures.

In addition to our capital expenditure, in November 2021, we acquired CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF from Saol. Under the terms of the agreement, we paid Saol a $95 million upfront payment, and agreed to pay up to an additional $50 million of contingent consideration subject the achievement of sales thresholds for the period commencing on the acquisition date and ending on December 31, 2034. During 2023, we made the first payment of the contingent consideration in the amount of $3.0 million following achievement of the first sales threshold. The second sales threshold was met and the second $3.0 million milestone payment was paid during February 2024. We may be entitled to up to a $3.0 million credit deductible from the contingent consideration payments due for the years 2024 through 2027, subject to certain conditions as defined in the agreement between the parties. During 2023, the entitlement for the credit was not met. In addition, we acquired inventory in the amount of $14.2 million and agreed to pay the consideration to Saol in ten quarterly installments of $1.5 million each or the remaining balance at the final installment. Through December 31, 2023, we paid a total of $12.0 million on account of such inventory commitment and we expect to pay the outstanding balance through the first half of 2024. We also assumed certain of Saol's liabilities for the future payment of royalties (some of which are perpetual) and milestone payments to third parties subject to the achievement of corresponding CYTOGAM related net sales thresholds and milestones. The outstanding balance of the contingent consideration, the inventory, royalties and milestone liabilities as of December 31, 2023, totaled $67.3 million. During the next 12 months we anticipate paying approximately $15.0 million on account of such contingent consideration, inventory related liability and the assumed liabilities, which payments are expected to be funded by our existing financial resources and cash to be generated through our operational activities. Payments on account of such liabilities expected to be made beyond the next 12 months are expected to be funded from expected cash to be generated by our operating activities, and to the extent required, raising additional capital through the issuance of equity or debt. For additional information also see above under "Key Components of Our Results of Operations—*Business Combination"* and Note 18e to our consolidated financial statements included in this Annual Report.

We have entered into long-term lease agreements with respect to office facility, storage spaces, collection center, vehicles and certain office equipment. The terms of such lease arrangements are between 3 to 20 years. The outstanding lease obligation as of December 31, 2023 totaled $8.8 million. For additional information see Note 15 to our consolidated financial statements included in this Annual Report.

We are also obligated to make certain severance or pension payments to our Israeli employees upon their retirement in accordance with Israeli law. For additional information, see "Post-Employment Benefits Liabilities" and Note 2l and Note 17 to our consolidated financial statements included in this Annual Report.

We believe our current cash and cash equivalents and expected future cash to be generated by our operational activities will be sufficient to satisfy our liquidity requirements for at least the next 12 months.

Credit Facility and Loan Agreement with Bank Hapoalim B.M.

In connection with the acquisition of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF from Saol, on November 15, 2021, we secured a $40 million of debt facility from Bank Hapoalim B.M., which was comprised of a $20 million five-year loan and a $20 million short-term revolving credit facility. The long-term loan bore interest at a rate of SOFR + 2.18% and was repayable in 54 equal monthly installments commencing on June 16, 2022. In September 2023, we repaid in full the outstanding balance of the $20 million five-year loan.

The credit facility was in effect for an initial period of 12 months, thereafter, on January 1, 2023, the credit facility was reduced to NIS 35 million (equivalent to approximately $10 million) and extended for an additional period of 12 months and subsequently on January 1, 2024, it was extended for an additional period of 12 months. Borrowings under the credit facility accrue interest at a rate of PRIME + 0.55 and are repayable no later than 12 months from the date advanced. We are required to pay Bank Hapoalim an annual fee of 0.275% for the credit allocation. The terms of the credit facility include certain financial covenants, including that we maintain: (i) minimum equity capital of 30% of the balance sheet and no less than $120 million, examined on a quarterly basis, (ii) a maximum working capital to debt ratio of 0.8, examined on a quarterly basis, and (iii) a minimum debt coverage ratio of 1.1 during 2022-2024 and 1.25 in 2025 and onwards, examined on an annual basis. In addition, the terms of the credit facility contains certain restrictive covenants including, among others, limitations on restructuring, the sale of purchase of assets, material licenses, certain changes of control and the creation of floating charges over our property and assets. In addition, we undertook not to create any first ranking floating charge over all or materially all of our property and assets in favor of any third party unless certain conditions, as defined in the loan agreement, have been satisfied.

Cash Flows from Operating Activities

Net cash provided by operating activities was $4.3 million for the year ended December 31, 2023. This net cash provided by operating activities was generated through the sales of our commercial products, mainly KEDRAB and CYTOGAM, as well as cash generated from royalties payable by Takeda on account of their GLASSIA sales, net of our operational costs.

Net cash provided by operating activities was $28.6 million for the year ended December 31, 2022. This net cash provided by operating activities was generated through the sales of our commercial products, mainly CYTOGAM and KEDRAB, as well as cash generated for royalties payable by Takeda on account of their GLASSIA sales, net of our operational costs.

Net cash used in operating activities was $8.8 million for the year ended December 31, 2021. This net cash used in operating activities reflects net loss of $2.2 million, $7.7 million for non-cash income and expenses, $14.4 million increase in assets, net of liabilities, and $0.1 million of interest income, net of interest and tax expenses paid in cash.

Cash Flows from Investing Activities

Net cash used in investing activities was $5.8 million for the year ended December 31, 2023, which comprises of capital expenditures primarily associated with the maintenance and improvements of our facilities and the construction of new plasma collection center in Uvalde, Texas.

Net cash used in investing activities was $3.8 million for the year ended December 31, 2022, which comprises of capital expenditures.

Net cash used in investing activities was $61.1 million for the year ended December 31, 2021, which comprises of $96.4 million related to the Saol and B&PR acquisitions, $39.1 million gained from disposition of short-terms investment and $3.7 million of capital expenditures.

Cash Flows from Financing Activities

Net cash provided by financing activities was $22.7 million for the year ended December 31, 2023, mainly due to net proceeds from our September 2023 private placement to the FIMI Opportunity Funds of an aggregate 12.6 million ordinary shares at a price of $4.75 per share, for an aggregate net proceeds of $58.2 million, which was offset in part by the repayment of the outstanding balance of the five-year loan from Bank Hapoalim B.M in the amount of $17.4. In addition, net cash provided by financing activities for the year ended December 31, 2023 includes the payment to Saol of $3.0 million on account of the contingent consideration for the first sales threshold and $6.0 million on account of the acquired inventory liability, as well as $1.5 million on account of the first sales milestone payment and $6.8 million on account of the $8.5 million milestone payment due upon the completion of the technology transfer of CYTOGAM manufacturing to our manufacturing facility in Israel and obtaining the FDA approval for the manufacturing of CYTOGAM at our manufacturing facility in Israel (the balance of $1.7 million on account of the $8.5 million milestone payment was paid and accounted for as cash flows from operating activities).

Net cash used in financing activities was $9.3 million for the year ended December 31, 2022, and is mainly related to payments made on account of the inventory related liability and assumed liabilities as a result of the acquisition of CYTOGAM, HEPGAM B, VARIZIG and WINRHO SDF as well as principal repayments on the long-term loan from Bank Hapoalim.

Net cash provided by financing activities was $18.6 million for the year ended December 31, 2021 and is mainly related to the receipt of the long-term loan from Bank Hapoalim.

Critical Accounting Policies and Estimates

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with IFRS as issued by the IASB. The preparation of these financial statements requires management to make estimates that affect the reported amounts of our assets, liabilities, revenues and expenses. Material accounting policies employed by us, including the use of estimates, are presented in the notes to the consolidated financial statements included elsewhere in this Annual Report. We periodically evaluate our estimates, which are based on historical experience and on various other assumptions that management believes to be reasonable under the circumstances. Critical accounting policies are those that are most important to the portrayal of our financial condition and results of operations and require management's subjective or complex judgments, resulting in the need for management to make estimates about the effect of matters that are inherently uncertain. If actual performance should differ from historical experience or if the underlying assumptions were to change, our financial condition and results of operations may be materially impacted. In addition, some accounting policies require significant judgment to apply complex principles of accounting to certain transactions, such as acquisitions, in determining the most appropriate accounting treatment.

A detailed description of our accounting policies is provided in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report. The following provides an overview of certain accounting policies that we believe are the most critical for understanding and evaluating our financial condition and results of operations.

Revenue Recognition

Revenues are recognized when the customer obtains control over the promised goods or services. In determining the amount of revenue from contracts with customers, we evaluate whether it is a principal or an agent in the arrangement. We are a principal when we control the promised goods or services before transferring them to the customer. In these circumstances, we recognize revenue for the gross amount of the consideration.

On the contract's inception date, we assess the goods or services promised in the contract with the customer and identify the performance obligations. Revenues are recognized at an amount that reflects the consideration to which an entity expects to be entitled in exchange for transferring goods or services to a customer.

We include variable consideration, such as variable prices, discounts, chargeback, rebates, adjustments to the net market price, volume rebates, in the transaction price, only when it is highly probable that its inclusion will not result in a significant revenue reversal in the future when the uncertainty has been subsequently resolved. For contracts that consist of more than one performance obligation, at contract inception we allocate the contract transaction price to each performance obligation identified in the contract on a relative stand-alone selling price basis.

Following the acquisition of CYTOGAM, WINRHO SDF, VARIZIG and HEPGAM B during November 2021, we, through our wholly owned subsidiary Kamada Inc., sell these products in the U.S. market to wholesalers/distributors for redistribution/sale of these products to other parties, such as hospitals and pharmacies. Revenue recognition occurs at a point in time when control of the product is transferred to the wholesalers/distributors, generally on delivery of the goods.

Our gross sales are subject to various deductions, which are primarily composed of rebates and discounts to group purchasing organizations, government agencies, wholesalers, health insurance companies and managed healthcare organizations. These deductions represent estimates of the related obligations, requiring the use of judgment when estimating the effect of these sales deductions on gross sales for a reporting period. These adjustments are deducted from gross sales to arrive at net sales. We monitor the obligation for these deductions on at least a quarterly basis and record adjustments when rebate trends, rebate programs and contract terms, legislative changes, or other significant events indicate that a change in the obligation is appropriate.

The following summarizes the nature of the most significant adjustments to revenues generated from the sales of these products in the U.S. market:

Wholesaler chargebacks:

We have arrangements with certain indirect customers whereby the customer is able to buy products from wholesalers at reduced prices. A chargeback represents the difference between the invoice price to the wholesaler and the indirect customer's contractual discounted price. Provisions for estimating chargebacks are calculated based on historical experience and product demand. The provision for chargebacks is recorded as a deduction from trade receivables on the consolidated statements of financial position.

Fees for service:

Consists of wholesaler/distributor fees associated with the redistribution of the products to hospitals and pharmacies. These fees are outlined in each wholesaler/distributor contract. The fees are invoiced on a monthly or quarterly basis by the wholesaler/distributor. The provisions for fees for service are recorded in the same period that the corresponding revenues are recognized.

We also generate revenue in the form of royalty payments, due from the grant of a license for the use of our IP, knowhow and patents. Royalty revenue is recognized when the underlying sales have occurred.

Business combinations and goodwill

In November 2021, we acquired a portfolio of four FDA-approved plasma-derived hyperimmune commercial products from Saol. For details, see "Item 5. Operating and Financial Review and Prospects—Key Components of Our Results of Operations—*Business Combination.*" The acquisition was accounted for as a business combination, for which a key element of the consideration was contingent.

The contingent consideration was recognized at fair value on the acquisition date and classified as a financial liability in accordance with IFRS 9. Contingent consideration is measured at fair value. The fair value is determined using valuation techniques and method, using future cash flows discounted. Subsequent changes in the fair value of the contingent consideration are recognized in profit or loss as finance income or finance expense.

As part of the acquisition, we also assumed certain of Saol's liabilities for the future payment of royalties (some of which are perpetual) and milestone payments to a third party subject to the achievement of corresponding CYTOGAM related net sales. Such assumed liabilities were accounted for as a financial liability on the acquisition date. Subsequently, the financial liability is measured at amortized cost, per IFRS 9. Remeasurement of the financial liability is recognized as finance income or expense in the statement of operations. For more information see Note 5 and Note 2d in our consolidated financial statements included in this Annual Report.

Inventories

Inventories are measured at the lower of cost and net realizable value. The cost of inventories is comprised of costs required to purchase raw materials and other indirect costs required to manufacture the product (including salaries), in addition, such costs may include the costs of purchase and shipping and handling. Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated selling costs.

We determine a standard manufacturing capacity for each quarter. To the extent the actual manufacturing capacity in a given quarter is lower than the predetermined standard, then a portion of the indirect costs which is equal to the product of the overall quarterly indirect costs multiplied by the quarterly manufacturing shortfall rate is recognized as costs of revenues. The determination of the standard manufacturing capacity is subject to significant assumptions such as expected demand for our products, expected industry sales growth and manufacturing schedules. Management's determination of deviations from quality standards is based on qualitative assessment, historical data and our past experience.

We periodically evaluate the condition and age of inventories and make provisions for slow-moving inventories accordingly. Unfavorable changes in market conditions may result in a need for additional inventory reserves that could adversely impact our gross margins. Conversely, favorable changes in demand could result in higher gross margins when we sell products.

We periodically assess the potential effect on inventory in cases of deviations from quality standards in the manufacturing process to identify potential required inventory write offs. Such assessment is subject to our professional judgment.

Inventory that is produced following a change in manufacturing process prior to final approval of regulatory authorities is subject to our estimates as to the probability of receipt of such approval. We periodically reassess the probability of such approval and the remaining shelf life of such inventory. If regulatory approval is not granted, the cost of this inventory will be charged to research and development expenses.

Impairment of Non-financial Assets

We evaluate the need to record an impairment of the carrying amount of non-financial assets whenever events or changes in circumstances indicate that the carrying amount is not recoverable. If the carrying amount of non-financial assets exceeds their recoverable amount, the assets are reduced to their recoverable amount. The recoverable amount is the higher of fair value less costs of sale and value in use. In measuring value in use, the expected future cash flows are discounted using a pre-tax discount rate that reflects the risks specific to the asset. The recoverable amount of an asset that does not generate independent cash flows is determined for the cash-generating unit to which the asset belongs. Impairment losses are recognized in profit or loss.

An impairment loss of an asset, other than goodwill, is reversed only if there have been changes in the estimates used to determine the asset's recoverable amount since the last impairment loss was recognized. Reversal of an impairment loss, as above, will not be increased above the lower of the carrying amount that would have been determined (net of depreciation or amortization) had no impairment loss been recognized for the asset in prior years and its recoverable amount. The reversal of impairment loss of an asset presented at cost is recognized in profit or loss. We had no impairment of non-financial assets in 2023.

Goodwill impairment

We review goodwill for impairment once a year, on December 31, or more frequently if events or changes in circumstances indicate that there is an impairment.

Goodwill is tested for impairment by assessing the recoverable amount of the cash-generating unit (or group of cash-generating units) to which the goodwill has been allocated. An impairment loss is recognized if the recoverable amount of the cash-generating unit (or group of cash-generating units) to which goodwill has been allocated is less than the carrying amount of the cash-generating unit (or group of cash-generating units). Any impairment loss is allocated first to goodwill. Impairment losses recognized for goodwill cannot be reversed in subsequent periods.

The goodwill is attributed to the Proprietary Products segment, which represents the lowest level within the Company at which goodwill is monitored for internal management purposes.

As of December 31, 2023, we performed an assessment for goodwill impairment for our Proprietary Products segment, which is the level at which goodwill is monitored for internal management purposes, and concluded that the fair value of the Proprietary Products segment exceeds the carrying amount by approximately 16%. The carrying amount of goodwill assigned to this segment is $30.3 million.

When evaluating the fair value of the Proprietary Products segment, the Company used a discounted cash flow model which utilized Level 3 measures that represent unobservable inputs. Key assumptions used to determine the estimated fair value include: (a) internal cash flows forecasts for five years following the assessment date, including expected revenue growth, costs to produce, operating profit margins and estimated capital needs; (b) an estimated terminal value using a terminal year long-term future growth rate of -4.8% determined based on the long-term expected prospects of the reporting unit; and (c) a discount rate (post-tax) of 11.8 % which reflects the weighted-average cost of capital adjusted for the relevant risk associated with the Proprietary Products segment's operations.

Actual results may differ from those assumed in our valuation method. It is reasonably possible that our assumptions described above could change in future periods. If any of these were to vary materially from our plans, we may record impairment of goodwill allocated to the Proprietary Products segment reporting unit in the future. A hypothetical decrease in the growth rate of 1% or an increase of 1% to the discount rate would have reduced the fair value of the Proprietary Products segment reporting unit by approximately $4.3 million and $21.0 million, respectively. The sensitivity analysis described above did not lead to an increase of the recoverable amount over the carrying amount. Based on our assessment as of December 31, 2023, no goodwill was determined to be impaired. For more information see Note 11 to our consolidated financial statements included in this Annual Report for more details.

Research and development costs

Research and development expenditures are recognized in profit or loss when incurred and include preclinical and clinical costs (as well as cost of materials associated with the development of new products or existing products for new therapeutic indications). In addition, these costs include additional product development activities with respect to approved and distributed products as well as post marketing commitment research and development activities.

Since our development projects are often subject to regulatory approval procedures and other uncertainties, the conditions for the capitalization of costs incurred before receipt of approvals are not normally satisfied and therefore, development expenditures are recognized in profit or loss when incurred.

Share-based Payment Transactions

Our employees and directors are entitled to remuneration in the form of equity-settled share-based payment transactions (options and restricted share units).

The cost of equity-settled transactions is measured at the fair value of the equity instruments granted at grant date. We use the binomial model when estimating the grant date fair value of equity settled share options. We selected the binomial option pricing model as the most appropriate method for determining the estimated fair value of our share-based awards without market conditions. We use the share price at the grant date when estimating the grant date fair value of equity settled restricted share units.

The determination of the grant date fair value of options using an option pricing model is affected by estimates and assumptions regarding a number of complex and subjective variables. These variables include the expected volatility of our share price over the expected term of the options, share option exercise and cancellation behaviors, expected exercise multiple, risk-free interest rates, expected dividends and the price of our ordinary shares on the TASE (or Nasdaq for persons who are subject to U.S. federal income tax), which are estimated as follows:

- *Expected Life*. The expected life of the share options is based on historical data, and is not necessarily indicative of the exercise patterns of share options that may occur in the future.
- *Volatility*. The expected volatility of the share prices reflects the assumption that the historical volatility of the share prices on the TASE is reasonably indicative of expected future trends.
- *Risk-free interest rate*. The risk-free interest rate is based on the yields of non-index-linked Bank of Israel treasury bonds with maturities similar to the expected term of the options for each option group.
- *Expected forfeiture rate*. The post-vesting forfeiture rate is based on the weighted average historical forfeiture rate.
- *Dividend yield and expected dividends*. We have not recently declared or paid any cash dividends on our ordinary shares and do not intend to pay any cash dividends. We have therefore assumed a dividend yield and expected dividends of zero.
- *Share price*. The price of our ordinary shares on the TASE (or Nasdaq for persons who are subject to U.S. federal income tax) used in determining the grant date fair value of options is based on the price on the grant date.

If any of the assumptions used in the binomial model change significantly, share-based compensation for future awards may differ materially compared with the awards granted previously.

The cost of equity-settled transactions is recognized in profit or loss, together with a corresponding increase in equity, during the period which the performance and/or service conditions are to be satisfied, ending on the date on which the relevant grantee become fully entitled to the award. The cumulative expense recognized for equity-settled transactions at the end of each reporting period until the vesting date reflects the extent to which the vesting period has expired and our best estimate of the number of equity instruments that will ultimately vest. The expense or income recognized in profit or loss represents the change between the cumulative expense recognized at the end of the reporting period and the cumulative expense recognized at the end of the previous reporting period.

No expense is recognized for awards that do not ultimately vest.

If we modify the conditions on which equity-instruments were granted, an additional expense is recognized for any modification that increases the total fair value of the share-based payment arrangement or is otherwise beneficial to the grantee at the modification date.

If a grant of an equity instrument is cancelled, it is accounted for as if it had vested on the cancellation date, and any expense not yet recognized for the grant is recognized immediately. However, if a new grant replaces the cancelled grant and is identified as a replacement grant on the grant date, the cancelled and new grants are accounted for as a modification of the original grant, as described above.

Post-employment Benefits Liabilities

Our post-retirement benefit plans are normally financed by contributions to insurance companies and classified as defined contribution plans or as defined benefit plans.

We operate a defined benefit plan in respect of severance pay pursuant to the Israeli Severance Pay Law, 1963. See Note 2l and Note 17 to our consolidated financial statements included in this Annual Report for more details.

The present value of our severance pay depends on a number of factors that are determined on an actuarial basis using a number of assumptions. The assumptions used in determining the net cost or income for severance pay and plan assets include a discount rate. Any changes in these assumptions will impact the carrying amount of severance pay and plan assets.

Other key assumptions inherent to the valuation include employee turnover, inflation, expected long term returns on plan assets and future payroll increases. The expected return on plan assets is determined by considering the expected returns available on assets underlying the current investments policy. These assumptions are given a weighted average and are based on independent actuarial advice and are updated on an annual basis. Actual circumstances may vary from these assumptions, giving rise to a different severance pay liability.

A sensitivity analyses was performed based on reasonably possible changes of the principal assumptions (discount rate and future salary increases) underlying the defined benefit plan.

In the event that the discount rate would be one percent higher or lower, and all other assumptions were held constant, the defined benefit obligation would decrease by $92,000 or increase by $124,000, respectively.

In the event that the expected salary growth would increase or decrease by one percent, and all other assumptions were held constant, the defined benefit obligation would increase by $118,000 or decrease by $87,000, respectively

As of August 2022, Kamada Inc, our U.S. wholly owned subsidiary has a 401(k) defined contribution plan covering certain employees in the U.S. All eligible employees may elect to contribute up to 100% of their annual compensation to the plan through salary deferrals, subject to Internal Revenue Service limits. For the year ended December 31, 2023, the contribution limit was $22,500 per year (for certain employees over 50 years of age the maximum contribution was $30,000 per year). The U.S. Subsidiary matches 3% of employee contributions up to the plan with no limitation.

Taxes on income

Current and Deferred taxes

Taxes on income in profit or loss comprise of current taxes, deferred taxes and taxes in respect of prior years, which are mainly recognized in profit or loss.

Deferred tax assets are reviewed at the end of each reporting period and reduced to the extent that it is not probable that they will be utilized. Deductible carryforward losses and temporary differences for which deferred tax assets had not been recognized are reviewed at the end of each reporting period and a respective deferred tax asset is recognized to the extent that their utilization is probable.

We operate in multiple tax jurisdictions. Deferred taxes are offset in the statement of financial position if there is a legally enforceable right to offset a current tax asset against a current tax liability and the deferred taxes relate to the same taxpayer and the same taxation authority.

As of December 31, 2023, we did not record a deferred tax asset for the remaining carry forward losses due to estimation that their utilization in the foreseeable future is not probable.

Uncertain tax positions

We evaluate potential uncertain tax positions, including additional tax and interest expenses, and recognize a provision when it is more probable than not that we will have to use our economic resources to pay such obligation.

As of December 31, 2023, and 2022, the application of IFRIC 23 did not have a material effect on the financial statements.

Leases

We account for a contract as a lease according to IFRS 16, "Leases" ("Lease Standard"), when the contract terms convey the right to control the use of an identified asset for a period of time in exchange for consideration.

On the inception date of the lease, we determine whether the arrangement is a lease or contains a lease, while examining if it conveys the right to control the use of an identified asset for a period of time in exchange for consideration. In our assessment of whether an arrangement conveys the right to control the use of an identified asset, we assess whether we have the following two rights throughout the lease term:

(a) The right to obtain substantially all the economic benefits from use of the identified asset; and

(b) The right to direct the identified asset's use.

For leases in which we are the lessee, we recognize on the commencement date of the lease a right-of-use asset and a lease liability, excluding leases whose term is up to 12 months and leases for which the underlying asset is of low value. For these excluded leases, we have elected to recognize the lease payments as an expense in profit or loss on a straight-line basis over the lease term. In measuring the lease liability, we have elected to apply the practical expedient in IFRS 16 and do not separate the lease components from the non-lease components (such as management and maintenance services, etc.) included in a single contract.

On the commencement date, the lease liability includes all unpaid lease payments discounted at the interest rate implicit in the lease, if that rate can be readily determined, or otherwise using our incremental borrowing rate. After the commencement date, we measure the lease liability using the effective interest rate method.

On the commencement date, the right-of-use asset is recognized in an amount equal to the lease liability plus lease payments already made on or before the commencement date and initial direct costs incurred less any lease incentives received. The right-of-use asset is measured applying the cost model and depreciated over the shorter of its useful life or the lease term. We test for impairment of the right-of-use asset whenever there are indications of impairment pursuant to the provisions of IAS 36.

Lease modifications are mostly for the extension of existing lease contracts. Thus, they do not reduce the scope of the lease or result in a separate lease. Under those modifications, we re-measure the lease liability based on the modified lease terms using a revised discount rate as of the modification date and record the change in the lease liability as an adjustment to the right-of-use asset.

For additional information, see Note 2i and Note 15 to our consolidated financial statements included in this Annual Report.

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

The following table sets forth certain information relating to our executive officers and directors as of March 1, 2024.

Name	Age	Position
Executive Officers:		
Amir London	55	Chief Executive Officer
Chaime Orlev	53	Chief Financial Officer
Eran Nir	51	Chief Operating Officer
Yael Brenner	60	Vice President, Quality
Hanni Neheman	54	Vice President, Marketing & Sales
Nir Livneh	45	Vice President, General Counsel and Corporate Secretary
Orit Pinchuk	58	Vice President, Regulatory Affairs and PVG
Liron Reshef	53	Vice President, Human Resources
Jon Knight	58	Vice President, US Commercial Operations
Shavit Beladev	53	Vice President, Plasma Operations
Boris Gorelik	43	Vice President, Business Development and Strategic Programs
Directors:		
Lilach Asher-Topilsky(*)(***)	53	Chair of the Board of Directors, Chair of the Strategy Committee
Uri Botzer(*)(***)	35	Director
Ishay Davidi(*)	62	Director
Prof. Benjamin Dekel(*)(**)	57	External Director
Karnit Goldwasser(*)	47	Director
Assaf Itshayek(*)(**)	51	External Director, Chairman of Audit Committee, Chairman of Compensation Committee
Lilach Payorski(*)(**)	50	Director
Leon Recanati(*)	75	Director
David Tsur(*)(***)	73	Director

(*) Independent director under the Nasdaq listing requirements.

(**) Member of the Audit Committee and the Compensation Committee.

(***) Member of the Strategy Committee.

Executive Officers

Amir London has served as our Chief Executive Officer since July 2015. Prior to that, Mr. London served as our Senior Vice President, Business Development from December 2013. Mr. London brings with him over 25 years of senior management and international business development experience. From 2011 to 2013, Mr. London served as the Chief Operating Officer of Fidelis Diagnostics, a U.S.-based provider of innovative in-office medical diagnostic services. Earlier in his career, from 2009 to 2011, Mr. London was the Chief Executive Officer of Promedico, an Israeli-based $350 million healthcare distribution company, and from 2006 to 2009 he was the General Manager of Cure Medical, providing contract manufacturing services for clinical studies, as well as home-care solutions. From 1995 to 2006, Mr. London was a Partner with Tefen, an international publicly-traded operations management consulting firm, responsible for the firm's global biopharma practice. Mr. London holds a B.Sc. degree in Industrial and Management Engineering from the Technion – Israel Institute of Technology.

Chaime Orlev has served as our Chief Financial Officer since December 2017 and he will be transitioning out of this role to pursue other opportunities, following the filing of this Annual Report. Prior to that, Mr. Orlev had served in senior finance roles for more than 20 years, with approximately 12 years spent in the life sciences industry. Previously, from September 2016 to November 2017, Mr. Orlev served as Chief Financial Officer and Vice President Finance and Administration at Bioblast Pharma Ltd. (Nasdaq: ORPN), a clinical-stage, biotechnology company. Prior to that, from 2010, Mr. Orlev served as Vice President Finance and Administration at Chiasma (Nasdaq: CHMA), a clinical stage biopharmaceutical company, in which role Mr. Orlev led the company's initial public offering and listing on Nasdaq. Mr. Orlev is a certified public accountant in Israel, holds an MBA degree from the Recanati Graduate School of Business Administration at the Tel Aviv University and a BA degree in Business Administration from the College of Management in Israel.

Eran Nir has served as our Chief Operating Officer since March 2022, overseeing our operations and research and development activities. Prior to that Mr. Nir served as our Vice President, Operations since November, 2016. Mr. Nir has over 20 years of operations management experience in the pharmaceutical and medical industries. Mr. Nir's previous roles include management of Teva Pharmaceutical Industries' plant in Jerusalem from 2002 to 2011, VP Operations of Amelia Cosmetics from 2014 to 2015 and management of a medical equipment plant of Philips Medical Systems from 2015 to 2016. Mr. Nir's experience spans across the management of large-scale FDA and EMA- approved manufacturing facilities, tech-transfer of new products from development to production and the implementation of operational excellence systems. Mr. Nir holds a B.Sc. degree in Industrial and Management Engineering and an MBA degree, both from Ben-Gurion University.

Yael Brenner has served as our Vice President, Quality since March 2015. Ms. Brenner has more than 25 years of experience in Quality Management, including Quality Assurance and Quality Control managerial positions in the pharmaceutical industry. Prior to joining Kamada, from 2007 to 2015, Ms. Brenner was at Teva Pharmaceuticals Industries, lastly as Senior Director Quality Operations of Teva's Kfar Sava Site, managing over 400 employees in Quality Assurance, Quality Control and Regulatory Affairs. Ms. Brenner holds B.Sc. and M.Sc. degrees in Chemistry from the Technion - Israel Institute of Technology, and she is a Certified Quality Engineer (CQE) from the American and Israeli Societies for Quality.

Hanni Neheman has served as our Vice President, Marketing & Sales since January 2020. Ms. Neheman joined us in August 2014 and served as Head of Business Operations, Israel. Ms. Neheman has more than 20 years of experience in different positions in the field of marketing and sales in the pharmaceutical industry. Prior to joining us, Ms. Neheman served as a Commercial Manager at Neopharm Israel. Ms. Neheman holds a B.A. degree in Occupational Therapy from the Technion Israel Institute of Technology and Executive M.B.A degree from Derby University.

Nir Livneh has served as our VP General Counsel and Corporate Secretary since May 2023. Mr. Livneh previously served as our General Counsel and Corporate Secretary, from 2010-2018. Prior to rejoining Kamada, Mr. Livneh served as Vice President of Legal Affairs at Purple Biotech Ltd. Previously, Mr. Livneh served as Legal Counsel at ICL Group Ltd. and General Counsel of PolyPid Ltd. Mr. Livneh is a member of the Israel Bar Association and holds an LL.B. (Bachelor of Law) and a B.A. degree in Business Administration from the Reichman University, Herzliya, Israel, and an LL.M degree from Tel Aviv University, Israel.

Orit Pinchuk has served as our Vice President, Regulatory Affairs and PVG since October 2014. Ms. Pinchuk has experience of more than 25 years in the pharmaceutical industry in key positions that cover, among others, disciplines of Regulatory Affairs and Compliance. Prior to joining Kamada, from 1993 to 2014, Ms. Pinchuk was at Teva Pharmaceuticals Industries, where she served as Director of Compliance and Regulatory Affairs, Operation Israel and Senior Director Regulatory Affairs, Research and Development and Operation Israel. Ms. Pinchuk has experience working with the FDA, EMA and the Canadian Health Authorities. Ms. Pinchuk holds a B.Tech degree in Textile Chemistry from Shenkar College for Engineering and Design and M.Sc. degree in Applied Chemistry from the Hebrew University of Jerusalem.

Liron Reshef joined us as our Vice President, Human Resources in January 2023. Ms. Reshef has over 20 years of experience in the field of human resources in senior Human Resources positions of global companies in different industries. From 2018 to 2021, Ms. Reshef served as EVP Human Resources of TAT Technologies and from 2014 to 2018, she served as VP Human Resources of Evogene. Earlier in her career, Ms. Reshef worked in senior HR positions for Frutarom, Solbar Industries, Comverse Technology and TICI Software Systems. Ms. Reshef is a certified Coach, specialized in personal coaching, career development and managers' coaching. Ms. Reshef holds a B.A degree. in Economics and Political Science from Bar-Ilan University and MBA degree, with specialization in Behavioral Sciences, from Ben-Gurion University, Israel.

Jon Knight has served as our Vice President of US Commercial Operations since March 2022. Mr. Knight has 25 years of Life Sciences experience, primarily focusing on commercializing innovative specialty plasma-products. Prior to joining us, Mr. Knight served in a variety of commercial leadership positions. Previously Mr. Knight was responsible for Trade Relations at TherapeuticsMD launching three innovative products into the U.S. market. Mr. Knight's professional background also includes leadership positions at Prometic Life Sciences, CIS by Deloitte, Cardinal Health, Cangene BioPharma and Nabi Biopharmaceuticals. Mr. Knight received an MBA from Colorado State University and a B.A. in Biology from Colorado Mesa University.

Shavit Beladev has served as our Vice President, Plasma Operations since June 2022. Ms. Beladev has been with us for over 20 years in increasingly senior positions, most recently as Director of Business Development. Ms. Beladev previously served in management roles responsible for International Sales, Key Accounts Management and Plasma Procurement. Since the establishment of Kamada Plasma in early 2021, Ms. Beladev's extended responsibilities also included overseeing the operation of the Company's plasma collection center in Beaumont, Texas, and the advance towards the opening of new centers. Ms. Beladev holds a BA degree in Economics and Business Administration from Ben-Gurion University, Israel.

Boris Gorelik has served as our Vice President, Business Development and Strategic Programs since June 2022. Prior to that, Mr. Gorelik served as our Director of Business Development from April 2020. Mr. Gorelik has over 14 years of Business Development and M&A experience, most of it in the pharmaceutical industry. Prior to joining us, Mr. Gorelik was Senior Director of Global Business Development and Strategy with Teva Pharmaceutical Industries, Ltd. Prior to his tenure at Teva, Mr. Gorelik served in various legal, M&A, and transaction services-related roles in the Israeli law office of Goldfarb Seligman, as well as KPMG and Deloitte Israeli offices. Mr. Gorelik holds a L.L.B degree, B.A. degree in Accounting and MBA degree, all from Tel Aviv University.

Directors

Lilach Asher-Topilsky has served as a member of our board of directors since December 2019, as the Chair of our board of directors since August 2020, served as a member of our Compensation Committee from August 2020 until August 2023 and serves as a member of our Strategy Committee (as the Chair of the Strategy Committee since November 2023). Mrs. Asher Topilsky has been a Senior Partner in the FIMI Opportunity Funds, Israel's largest group of private equity funds, since December 2019. Mrs. Asher Topilsky currently serves as the chairman of G1 Security Systems Ltd. (TASE), Rimoni Industries Ltd. (TASE), SOS Ltd. Elyakim Ben Ari Group Ltd. and Amal and beyond Ltd. and as a director at Amiad Water Systems Ltd. (AIM), Ashot Ashkelon Industries Ltd. (TASE) and Tel Aviv University. Prior to joining FIMI, Mrs. Asher Topilsky served as the President and CEO of Israel Discount Bank (TASE), one of the leading banking groups in Israel, as the Chairman at IDBNY BANKCORP and as a director at IDB Bank New York from 2014 – 2019. Mrs. Asher Topilsky also served as the Chairman of Mercantile Bank from 2014 – 2016. Before that, Mrs. Asher Topilsky served as a member of the management of Bank Hapoalim (TASE) as Deputy CEO & Head of Retail Banking Division (2009 – 2013) & Head of Strategy & Planning Division (2007 – 2009). Mrs. Asher Topilsky served as a Strategy Consultant at The Boston Consulting Group (BCG, Chicago 1997 – 1998) and at Shaldor Strategy Consulting (Israel 1995 – 1996). Mrs. Asher Topilsky holds an M.B.A. degree from Kellogg School of Management, Northwestern University, Chicago, USA (1997), and a B.A. degree in Management and Economics from Tel Aviv University, Israel (Magna Cum Laude, 1994).

Uri Botzer has served as a member of our board of directors since December 2022. Mr. Botzer has been a Junior Partner in the FIMI Opportunity Funds, Israel's largest group of private equity funds, since 2019. Prior to joining FIMI, Mr. Botzer served as a lawyer at FISCHER (FBC & Co.). Mr. Botzer holds a B.A. degree in Business Administration and a LL.B. (Bachelor of Law), Cum Laude, from Reichman University, Herzliya.

Ishay Davidi has served on our board of directors since December 2019. Mr. Davidi is the Founder and has served as Chief Executive Officer of the FIMI Opportunity Funds, Israel's largest group of private equity funds, since 1996. Mr. Davidi currently serves as the Chairman of the Board of Directors of Polyram Plastic Industries Ltd (TASE) and Ashot Ashkelon Industries Ltd. (TASE). Mr. Davidi also serves as a director of Bet Shemesh Engines Ltd. (TASE), C. Mer Industries Ltd. (TASE), G1 Security Systems Ltd. (TASE), PCB Technologies Ltd. (TASE), Rekah Pharmaceutical Industries (TASE), SOS Ltd., GreenStream Ltd., Amiad Water Systems Ltd (AIM), Rimoni Industries Ltd. (TASE), Elyakim Ben-Ari Group Ltd. and Amal and beyond Ltd. Mr. Davidi previously served as the Chairman of the board of directors of Infinya Ltd. (TASE), Inrom, Retalix (previously traded on NASDAQ and TASE) and Tefron Ltd. (NYSE and TASE) and as a director of Gilat Satellite Networks Ltd. (NASDAQ and TASE), Pharm Up Ltd (TASE), Ham-Let Ltd. (TASE), Ormat Industries Ltd. (previously traded on TASE), Lipman Electronic Engineering Ltd. (NASDAQ and TASE), Merhav Ceramic and Building Materials Center Ltd. (NASDAQ and TASE), Orian C.M. Ltd. (TASE), Ophir Optronics Ltd., Overseas Commerce Ltd. (TASE), Scope Metals Group Ltd. (TASE), Tadir-Gan (Precision Products) 1993 Ltd. (TASE) and Formula Systems Ltd. (NASDAQ and TASE). Prior to establishing FIMI, from 1993 until 1996, Mr. Davidi was the Founder and Chief Executive Officer of Tikvah Fund, a private Israeli investment fund. From 1992 until 1993 Mr. Davidi served as the Chief Executive Officer of Zer Science Industries Ltd. Mr. Davidi holds an M.B.A. degree from Bar Ilan University, Israel, and a B.Sc. degree, with honors, in Industrial Engineering from the Tel Aviv University, Israel.

Prof. Benjamin Dekel has served as an external director (within the meaning of the Companies Law) since August 2023 and serves as a member of our Audit Committee and Compensation Committee. Prof. Dekel currently serves as the Founder and Chief Scientist of RenoVate Biopharmaceuticals Ltd., as director at Sagol Center for Regenerative Medicine, Tel Aviv University; as Vice-Dean, School of Medicine, Tel Aviv University; Chief, Pediatric Nephrology and Pediatric Stem Cell Research Institute, Sheba Medical Center; as a member of the Higher Committee on Cell and Gene Therapy, Israel Ministry of Health; and as a member of the Scientific Advisory Board, Stemrad, Ltd. From June 2009 until June 2020, Prof. Dekel served as Chief Scientist and a member of the board of directors of KidneyCure Inc. In 2011, Prof. Dekel Served as a Visiting Scholar at Stanford University. From January 2003 to January 2005, Prof. Dekel Served as a Fellow at the Weizmann Institute. Prof. Dekel holds an MD degree in Medicine from the Technion — Israel Institute of Technology and a PhD in Immunology & Transplantation Biology from the Weizmann Institute.

Karnit Goldwasser has served on our board of directors since December 2019 and served as a member of our Audit Committee and Compensation Committee from January 2020 until August 2023. Ms. Goldwasser serves as an independent consultant and environmental engineer for various agencies and organizations. Ms. Goldwasser is a director at Delek San Recycling Ltd. (since December 2016). Ms. Goldwasser previously served as a director at ELA Recycling Corporation (2015 – September 2021), Orian DB Schenker (2017 – 2020) and at the government-owned Environmental Services Company Ltd., as chair of the Safety Committee (2010 – 2016), and as a member of the Tel Aviv-Jaffa City Council, holding the environmental portfolio (2013 – 2016). Ms. Goldwasser also served as a director in several Tel Aviv-Jaffa municipality corporations: Dan Municipal Sanitation Association, as chair of the audit committee; Tel Aviv-Jaffa Economic Development Authority; and Ganei Yehoshua Co. Ltd. Ms. Goldwasser holds a B.Sc. degree in Environmental Engineering, focusing on chemistry, mathematics and environmental engineering, a M.Sc. degree in Civil Engineering, specializing in Hydrodynamics and Water Resources, both from the Technion — Israel Institute of Technology, and a M.A. degree in Public Policy and Administration from the Lauder School of Government, Diplomacy and Strategy, IDC Herzliya. Ms. Goldwasser also completed the Directors Program at LAHAV, School of Management, Tel Aviv University.

Assaf Itshayek has served as an external director (within the meaning of the Companies Law) since August 2023 and is the Chairman of our Audit Committee and Compensation Committee. Mr. Itshayek has over 15 years of hi-tech industry experience in senior management and finance executive positions in different industries (including online, fintech and energy). Mr. Itshayek currently serves as a member of the board of directors of GoTo Global Ltd., Qira Ltd. and Trinity Audio Ltd. From June 2021 until October 2022, Mr. Itshayek served as the chief executive officer of NeraTech Media Ltd. Prior thereto, from November 2012 until June 2021, Mr. Itshayek was at Somoto Ltd. (TASE: SMTO), initially as the chief financial officer and from December 2017, as the chief executive officer. Prior thereto, Mr. Itshayek served as the chief financial officer of BlueSnap Inc. (from February 2021 until January 2021) and Digital Power Corporation Ltd. (June 2009- May 2011) and served as the corporate controller of Metalink Ltd. from June 2006 until August 2008. From December 1999 until July 2006, Mr. Itshayek served as a TMT senior audit manager at Deloitte Brightman Almagor Zohar & Co., a Firm in the Deloitte Global Network. Mr. Itshayek holds a B.A. degree in Business Administration and Accountancy from the College of Management and an M.B.A. degree from Tel Aviv University.

Lilach Payorski has served on our board of directors since December 2021, and serves as a member of our Audit Committee. Ms. Payorski served as the Chair of our Audit Committee from December 2021 to October 2023.Ms. Payorski served as the Chief Financial Officer of Tyto Care Ltd. from November 2022 until March 2023. Prior to that, Ms. Payorski served as the Chief Financial Officer of Stratasys Ltd (NASDAQ: SSYS), a developer and manufacturer of 3D printers and additive solutions, from January 2017 to February 2022. From December 2012 until December 2016, Ms. Payorski served as Senior Vice President, Corporate Finance at Stratasys. From December 2009 to December 2012, Ms. Payorski served as Head of Finance at PMC-Sierra (NASDAQ: PMCS), a company operating in the semiconductors industry, which was subsequently acquired by Microsemi Corporation. Prior to that, from March 2005 to December 2009, Ms. Payorski served as Compliance Controller at Check Point Software Technologies Ltd. (NASDAQ: CHKP), a security company. Ms. Payorski also served as corporate controller at Wind River Systems (NASDAQ: WIND), a software company, which was subsequently acquired by Intel Corporation, from June 2003 to March 2005. Earlier in her career, from March 1997 to June 2003, Ms. Payorski worked as a chartered public accountant at Ernst & Young LLP, both in Israel and later in Palo Alto, CA. Ms. Payorski currently serves as the chairman of the audit committee of ODDITY Ltd. (NASDAQ: ODD) and Scodix Ltd. (TASE: SCDX). Ms. Payorski holds a B.A. degree in Accounting and Economics from Tel Aviv University. Ms. Payorski also completed the Board of Directors and Senior Corporate Officers Program at LAHAV, School of Management, Tel Aviv University.

Leon Recanati has served on our board of directors since May 2005, as the Chairman of our board of directors from March 2013 to August 2020, and served as the Chairman of our Compensation Committee from February 2019 until September 2023. Mr. Recanati currently serves as the Chairman of MadaTech, National Museum of Science Technology and Space in memory of Daniel and Mathilde Recanati. Mr. Recanati also serves as a member of the board of directors of Evogene Ltd., a plant genomics company listed on the TASE and New York Stock Exchange. Mr. Recanati is also a board member of the following private companies: GlenRock Israel Ltd., Gov, RelTech Holdings Ltd., Legov Ltd., Insight Capital Ltd., Shavit Capital Funds and Ofil Ltd. Mr. Recanati currently serves as the Chairman and Chief Executive Officer of GlenRock. Previously, Mr. Recanati was Chief Executive Officer and/or Chairman of IDB Holding Corporation Ltd., Clal Industries Ltd., Azorim Investment Development and Construction Co Ltd., Delek Israel Fuel Corporation and Super-Sol Ltd. Mr. Recanati also founded Clal Biotechnologies Industries Ltd., a biotechnology investment company operating in Israel. Mr. Recanati holds an M.B.A. degree from the Hebrew University of Jerusalem and Honorary Doctorates from the Technion — Israel Institute of Technology and Tel Aviv University.

David Tsur has served on our board of directors since our inception and serves as a member of our Strategy Committee. Mr. Tsur served as the Active Deputy Chairman on a half-time basis from July 2015 until December 31, 2019. Mr. Tsur served as our Chief Executive Officer from our inception until July 2015. Mr. Tsur currently serves on the Board of Directors of Kanabo Ltd. (LSE) and as a director of BioHarvest Sciences Inc. (CSE). Prior to co-founding Kamada in 1990, Mr. Tsur served as Chief Executive Officer of Arad Systems and RAD Chemicals Inc. Mr. Tsur previously served as the Chairman of the Board of Directors of CollPlant Ltd., a company listed on the TASE and OTC market. Mr. Tsur has also held various positions in the Israeli Ministry of Economy and Industry (formerly named the Ministry of Industry and Trade), including Chief Economist and Commercial Attaché in Argentina and Iran. Mr. Tsur holds a B.A. degree in Economics and International Relations and an M.B.A. degree in Business Management, both from the Hebrew University of Jerusalem.

Under a shareholders' agreement entered into on March 6, 2013, the Recanati Group, on the one hand, and the Damar Group, on the other hand, have each agreed to vote the ordinary shares beneficially owned by them in favor of the election of director nominees designated by the other group as follows: (i) three director nominees, so long as the other group beneficially owns at least 7.5% of our outstanding share capital, (ii) two director nominees, so long as the other group beneficially owns at least 5.0% (but less than 7.5%) of our outstanding share capital, and (iii) one director nominee, so long as the other group beneficially owns at least 2.5% (but less than 5.0%) of our outstanding share capital. In addition, to the extent that after the designation of the foregoing director nominees there are additional director vacancies, each of the Recanati Group and Damar Group have agreed to vote the ordinary shares beneficially owned by them in favor of such additional director nominees designated by the party who beneficially owns the larger voting rights in our company. See "Item 7. Major Shareholders and Related Party Transactions — Related Party Transactions — Shareholder Agreement."

B. Compensation

Aggregate Compensation of Directors and Officers

The aggregate compensation incurred by us in relation to our executive officers and directors, including share-based compensation, for the year ended December 31, 2023, was approximately $4.7 million. This amount includes approximately $0.24 million set aside or accrued to provide pension, severance, retirement or similar benefits or expenses, but does not include business travel, professional and business association dues and expenses reimbursed to executive officers, and other benefits commonly reimbursed or paid by companies in Israel.

From time to time, we grant options to our officers and directors and, in the past, granted restricted share units to our officers. We granted options to purchase an aggregate 202,000 of our ordinary shares to our officers and directors as a group during the year ended December 31, 2023. As of December 31, 2023, options to purchase 1,872,500 of our ordinary shares granted to our officers and directors as a group were outstanding, of which options to purchase 880,500 of our ordinary shares were vested, with a weighted average exercise price of NIS 20.49 per ordinary share. In addition, as of December 31, 2023, 1,875 restricted share units granted to our officers as a group were outstanding. For details regarding the beneficial ownership of our shares by our officers and directors, see "Item 6. Directors, Senior Management and Employees — Share Ownership."

Compensation of Directors

We pay our directors an annual fee and per-meeting fees in the maximum amounts payable from time to time for such fees by us under the Second and Third Addendums, respectively (or, to the extent any director is determined to have financial and accounting expertise and is deemed an expert director (in each case, within the meaning of the Companies Law and the regulations thereunder), under the Fourth Addendum) to the Israeli Companies Regulations (Rules Regarding Compensation and Expense Reimbursement of External Directors), 2000, or the Compensation Regulations. In accordance with the Compensation Regulations, we currently pay our directors an annual fee of NIS 92,460 (approximately $ 25,079) as well as a fee of NIS 3,560 (approximately $966) for each board or committee meeting attended in person, NIS 2,136 (approximately $580) for each board or committee meeting attended via telephone or videoconference and NIS 1,780 (approximately $483) for participation by written consent.

There are no arrangements or understandings between us, on the one hand, and any of our directors, on the other hand, providing for benefits upon termination of their service as directors of our company.

To our knowledge, there are no agreements and arrangements between any director and any third party relating to compensation or other payment in connection with their candidacy or service on our Board of Directors.

Compensation of Covered Executives

The following table presents information regarding compensation accrued in our financial statements for our five most highly compensated office holders (within the meaning of the Companies Law), namely our Chief Executive Officer, Chief Financial Officer, Vice President, Business Development and Strategic Programs, Chief Operating Officer and Vice President, US Commercial Operations, during or with respect to the year ended December 31, 2023. Each such office holder was covered by our directors' and officers' liability insurance policy and was entitled to indemnification and exculpation in accordance with indemnification and exculpation agreements, our articles of association and applicable law.

Name and Position	Salary[1]	Bonus[2]	Value of Options Granted[3]	Other[4]	Total
			(in thousands)		
Amir London *Chief Executive Officer*	$ 409	$ 176	$ 250	$ 26	$ 861
Chaime Orlev *Chief Financial Officer*	$ 291	$ 74	$ 122	$ 22	$ 509
Boris Gorelik *Vice President, Business Development and Strategic Programs*	$ 252	$ 50	$ 47	$ 108	$ 457
Eran Nir *Chief Operating Officer*	$ 276	$ 69	$ 55	$ (13)	$ 387
Jon Knight *Vice President,* US Commercial Operations	$ 237	$ 70	$ 43	$ -	$ 350

(1) Salary includes gross salary and fringe benefits.

(2) Bonuses includes annual bonuses. The annual bonus is subject to the fulfillment of certain targets determined for each year by the compensation committee and board of directors.
(3) The value of options is the expense recorded in our financial statements for the period ended December 31, 2023 with respect to all options granted to such executive officer.
(4) Cost of housing and personal expenses, and allowance for the use of a company car net of reimbursement by social security of certain salary expenses, each to the extent applicable.

Agreements with Five Most Highly Compensated Office Holders

We have entered into agreements with each of our five most highly compensated office holders (within the meaning of the Companies Law), listed below. The terms of employment or service of such office holders are directed by our compensation policy. See below "— Compensation Policy." Each of these agreements contains provisions regarding non-competition, confidentiality of information and assignment of inventions. The non-competition provision applies for a period that is generally 12 months following termination of employment. The enforceability of covenants not to compete in Israel and the United States is subject to limitations. Such office holders are entitled to an annual bonus subject to the fulfillment of certain targets determined for each year by the compensation committee and board of directors. In addition, our Israeli based executive officers are entitled to a company car, as well as sick pay, convalescence pay, manager's insurance and a study fund ("*keren hishtalmut*") and annual leave, all in accordance with Israeli law and our compensation policy for executive officers, and our U.S.-based executive officers are entitled to benefits customary to U.S. executives such as medical benefits and 401(k) plan, and in certain cases to relocation related remuneration.

Amir London, Chief Executive Officer. Mr. London has served as our Chief Executive Officer since July 2015. Prior to that and effective as of December 1, 2013, Mr. London served as our Vice President, Business Development. Mr. London's engagement terms as our Chief Executive Officer have been approved by our Compensation Committee, Board of Directors and shareholders. According to the terms of the agreement, either party may terminate the agreement at any time upon three months' prior written notice to the other party, and we may terminate the agreement immediately for cause in accordance with Israeli law.

Chaime Orlev, Chief Financial Officer. Effective as of October 1, 2017, we entered into an employment agreement with Mr. Chaime Orlev with respect to his employment as our Chief Financial Officer. Either party may terminate the agreement at any time upon three months' prior written notice to the other party, and we may terminate the agreement immediately for cause in accordance with Israeli law.

Boris Gorelik, Vice President, Business Development and Strategic Programs. Effective as of June 2022, we entered into a three-year employment agreement with Mr. Boris Gorelik in connection with his relocation to the U.S. and his employment as our Vice President of Business Development. Prior to that Mr. Gorelik served as our Director of Business Development from April 2020. Either party may terminate the agreement at any time upon three months' prior written notice to the other party, and we may terminate the agreement immediately for cause in accordance with U.S. law.

Eran Nir, Chief Operating Officer. Mr. Eran Nir has served our Chief Operating Officer since March 1, 2022. Prior to that and effective as of November 1, 2016, Mr. Nir served as our Vice President, Operations. According to the terms of his employment agreement, either party may terminate the agreement at any time upon two months' prior written notice to the other party, and we may terminate the agreement immediately for cause in accordance with Israeli law.

Jon Knight , Vice President, US Commercial Operations. Effective as of March15, 2022, we entered into an employment agreement with Mr. Jon Knight with respect to his employment as our Vice President, US Commercial Operations. Either party may terminate the agreement at any time upon three months' prior written notice to the other party, and we may terminate the agreement immediately for cause in accordance with U.S. law.

Other Executive Officers

We have entered into written employment agreements with the rest of our executive officers. The terms of employment of our executive office holders are directed by our compensation policy. See "— Compensation Policy." Each of these agreements contains provisions regarding non-competition, confidentiality of information and assignment of inventions. The non-competition provision applies for a period that is generally 12 months following termination of employment. The enforceability of covenants not to compete in Israel and the United States is subject to limitations. In addition, we are required to provide up to three months' notice prior to terminating the employment of such executive officers, other than in the case of a termination for cause. Each of our employment agreements with such executive officers provides for annual bonuses, which are subject to the fulfillment of certain targets determined for each year, and the executive officers may be also entitled to special bonuses upon the achievement of certain company milestones.

Compensation of Directors and Executive Officers under Israeli Law

Compensation Policy.

Under the Companies Law, a public company is required to adopt a compensation policy, which sets forth the terms of service and employment of office holders, including the grant of any benefit, payment or undertaking to provide payment, any exemption from liability, insurance or indemnification, and any severance payment or benefit. Such compensation policy must comply with the requirements of the Companies Law. The compensation policy must be approved at least once every three years, first, by our board of directors, upon recommendation of our compensation committee, and second, by the shareholders by a special majority. Our current compensation policy for executive officers and compensation policy for directors were each approved by our shareholders on December 22, 2022.

Compensation of Directors

Under the Companies Law, the compensation (including insurance, indemnification, exculpation and compensation) of our directors requires the approval of our compensation committee, the subsequent approval of the board of directors and, unless exempted under the regulations promulgated under the Companies Law, the approval of the shareholders at a general meeting. The approval of the compensation committee and board of directors must be in accordance with the compensation policy. In special circumstances, the compensation committee and board of directors may approve a compensation arrangement that is inconsistent with the company's compensation policy, provided that they have considered the same considerations and matters required for the approval of a compensation policy in accordance with the Companies Law, in which case the approval of the company's shareholders must be by a special majority (referred to as the "Special Majority for Compensation") that requires that either:

- a majority of the shares held by shareholders who are not controlling shareholders and shareholders who do not have a personal interest in such matter and who are present and voting at the meeting, are voted in favor of approving the compensation package, excluding abstentions; or

- the total number of shares voted by non-controlling shareholders and shareholders who do not have a personal interest in such matter that are voted against the compensation package does not exceed 2% of the aggregate voting rights in the company.

Where the director is also a controlling shareholder, the requirements for approval of transactions with controlling shareholders apply, as described above under "— Disclosure of Personal Interests of a Controlling Shareholder and Approval of Certain Transactions."

Compensation of Officers Other than the Chief Executive Officer

Pursuant to the Companies Law, the compensation (including insurance, indemnification and exculpation) of a public company's office holders (other than directors, which is described above, and the chief executive officer, which is described below) generally requires approval first by the compensation committee and second by the company's board of directors, according to the company's compensation policy. In special circumstances the compensation committee and board of directors may approve a compensation arrangement that is inconsistent with the company's compensation policy, provided that they have considered the same considerations and matters required for the approval of a compensation policy in accordance with the Companies Law and such arrangement must be approved by the company's shareholders by the Special Majority for Compensation. However, if the shareholders of the company do not approve a compensation arrangement with an executive officer that is inconsistent with the company's compensation policy, the compensation committee and board of directors may, in special circumstances, override the shareholders' decision, subject to certain conditions.

Under the Companies Law, an amendment to an existing arrangement with an office holder (other than the chief executive officer, which is described below) who is not a director requires only the approval of the compensation committee, if the compensation committee determines that the amendment is not material in comparison to the existing arrangement. However, according to regulations promulgated under the Companies Law, an amendment to an existing arrangement with an office holder (who is not a director) who is subordinate to the chief executive officer shall not require the approval of the compensation committee, if (i) the amendment is approved by the chief executive officer and the company's compensation policy determines that a non-material amendment to the terms of service of an office holder (other than the chief executive officer) will be approved by the chief executive officer and (ii) the engagement terms are consistent with the company's compensation policy. Under our compensation policy for executive officers and subject to applicable law, our chief executive officer may approve an immaterial amendment of up to 10% of the existing terms of office and engagement (as compared to those approved by the compensation committee) of an executive who is subordinate to the chief executive officer (who is not a director).

Compensation of Chief Executive Officer

The compensation (including insurance, indemnification and exculpation) of a public company's chief executive officer generally requires the approval of first, the company's compensation committee; second, the company's board of directors; and third (except for limited exceptions), the company's shareholders by the Special Majority for Compensation. If the shareholders of the company do not approve the compensation arrangement with the chief executive officer, the compensation committee and board of directors may override the shareholders' decision, subject to certain conditions. The compensation committee and board of directors approval should be in accordance with the company's compensation policy; however, in special circumstances, they may approve compensation terms of a chief executive officer that are inconsistent with such policy provided that they have considered the same considerations and matters required for the approval of a compensation policy in accordance with the Companies Law and that shareholder approval was obtained by the Special Majority for Compensation. Under certain circumstances, the compensation committee and board of directors may waive the shareholder approval requirement in respect of the compensation arrangements with a candidate for chief executive officer if they determine that the compensation arrangements are consistent with the company's stated compensation policy.

However, an amendment to an existing arrangement with an executive officer (who is not a director) requires only the approval of the compensation committee, if the compensation committee determines that the amendment is not material in comparison to the existing arrangement. Furthermore, according to regulations promulgated under the Companies Law, the renewal or extension of an existing arrangement with a chief executive officer shall not require shareholder approval if (i) the renewal or extension is not beneficial to the chief executive officer as compared to the prior arrangement or there is no substantial change in the terms and other relevant circumstances; and (ii) the engagement terms are consistent with the company's compensation policy and the prior arrangement was approved by the shareholders by the Special Majority for Compensation.

Where the office holder is also a controlling shareholder, the requirements for approval of transactions with controlling shareholders apply, as described above under "— Disclosure of Personal Interests of a Controlling Shareholders and Approval of Certain Transactions."

Exculpation, Insurance and Indemnification of Office Holders

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 the company's articles of association. Our articles of association include such a provision. However, we may not exculpate an office holder for an action or transaction in which a controlling shareholder or any other office holder (including an office holder who is not the office holder we have undertaken to exculpate) has a personal interest (within the meaning of the Companies Law). We may also 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 for the following liabilities, payments and expenses incurred for acts performed by him or her, as an office holder, either pursuant to an undertaking given by the company in advance of the act or following the act, provided its articles of association authorize such indemnification:

- a monetary 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 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. Such undertaking shall detail the foreseen events and amount or criteria mentioned above;

- reasonable litigation expenses, including reasonable attorneys' fees, incurred by the office holder (1) 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 (i) no indictment was filed against such office holder as a result of such investigation or proceeding; and (ii) no financial liability 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 (*mens rea*); and (2) 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 (*mens rea)*.

In addition, under the Companies Law, a company may insure an office holder against the following liabilities incurred for acts performed by him or her as an office holder, to the extent provided in the company's articles of association:

- a breach of a 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 monetary liability imposed on the office holder in favor of a third party.

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 the duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the office holder;
- an act or omission committed with intent to derive illegal personal benefit; or
- a fine or penalty levied against the office holder.

For the approval of exculpation, indemnification and insurance of office holders who are directors, see "— Compensation of Directors," for the approval of exculpation, indemnification and insurance of office holders who are not directors, see "—Compensation of Executive Officers" and for the approval of exculpation, indemnification and insurance of office holders who are controlling shareholders, see "— Fiduciary Duties and Approval of Specified Related Party Transactions under Israeli Law — Disclosure of Personal Interests of a Controlling Shareholder and Approval of Certain Transactions."

Our articles of association permit us to exculpate, indemnify and insure our office holders to the fullest extent permitted under the Companies Law (other than indemnification for litigation expenses in connection with a monetary sanction); provided that we may not exculpate an office holder for an action or transaction in which a controlling shareholder or any other office holder (including an office holder who is not the office holder we have undertaken to exculpate) has a personal interest (within the meaning of the Companies Law).

We have entered into indemnification and exculpation agreements with each of our current office holders exculpating them from a breach of their duty of care to us to the fullest extent permitted by the Companies Law (provided that we may not exculpate an office holder for an action or transaction in which a controlling shareholder or any other office holder (including an office holder who is not the office holder we have undertaken to exculpate) has a personal interest (within the meaning of the Companies Law)) and undertaking to indemnify them to the fullest extent permitted by the Companies Law (other than indemnification for litigation expenses in connection with a monetary sanction), to the extent that these liabilities are not covered by insurance. This indemnification is limited to events determined as foreseeable by our board of directors based on our activities, as set forth in the indemnification agreements. Under such agreements, the maximum aggregate amount of indemnification that we may pay to all of our office holders together is (i) for office holders who joined our company before May 31, 2013, the greater of 30% of the shareholders equity according to our most recent financial statements (audited or reviewed) at the time of payment and NIS 20 million, and (ii) for office holders who joined our company after May 31, 2013, 25% of the shareholders equity according to our most recent financial statements (audited or reviewed) at the time of payment.

We are not aware of any pending or threatened litigation or proceeding involving any of our office holders as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any office holder.

C. Board Practices

Board of Directors

Under our articles of association, the number of directors on our board of directors (including external directors) must be no less than five and no more than 11. Our board of directors currently consists of nine directors, including two external directors. All of our current directors qualify as "independent directors" under the Nasdaq listing requirements, such that we comply with the Nasdaq Listing Rule that requires that a majority of our board of directors be comprised of independent directors, within the meaning of Nasdaq Listing Rules.

Other than our external directors who are subject to special election requirements under the Companies Law, our directors are elected by the vote of a majority of the ordinary shares present, in person or by proxy, and voting at a shareholders' meeting. Each director (other than our external directors) holds office until the first annual general meeting of shareholders following his or her appointment, unless the tenure of such director expires earlier pursuant to the Companies Law or unless he or she is removed from office as described below.

Vacancies on our board of directors, including vacancies resulting from there being fewer than the maximum number of directors permitted by our articles of association, may generally be filled by a vote of a simple majority of the directors then in office. See "— External Directors" for a description of the procedure for the election of external directors.

A general meeting of our shareholders may remove a director (other than our external directors) from office prior to the expiration of his or her term in office by a resolution adopted by holders of a majority of our shares voting on the proposed removal, provided that the director being removed from office is given a reasonable opportunity to present his or her case before the general meeting. See "— External" for a description of the procedure for the removal of external directors.

External Directors

Under the Companies Law, companies incorporated under the laws of the State of Israel that are "public companies," must appoint at least two external directors who meet the qualification requirements in the Companies Law.

According to regulations promulgated under the Companies Law, a company whose shares are traded on certain stock exchanges outside Israel (including the Nasdaq Global Select Market, such as our company) that does not have a controlling shareholder and that complies with the requirements of the laws of the foreign jurisdiction where the company's shares are listed, as they apply to domestic issuers, with respect to the appointment of independent directors and the composition of the audit committee and compensation committee, may elect to exempt itself from the requirements of Israeli law with respect to the requirement to appoint external directors and related rules concerning the composition of the audit committee and compensation committee of the board of directors. If a company has elected to avail itself from the requirement to appoint external directors and at the time a director is appointed all members of the board of directors are of the same gender, a director of the other gender must be appointed. Accordingly, on January 30, 2017, following analysis of our qualification to rely on the exemption, our board of directors determined to adopt the exemption, following which we ceased to have external directors serving on our board of directors, and according to the terms of the relief, a majority of our directors were required to be independent directors (within the meaning of Nasdaq Listing Rules) and the composition of audit committee and compensation committee was required to comply with the requirements of the Nasdaq Listing Rules.

However, following the closing of the September 2023 private placement, FIMI Opportunity Funds became our controlling shareholder (within the meaning of the Companies Law), and as a result, we ceased to be entitled to rely on the relief from external directors and are required to comply with the Israeli law requirements relating to the appointment of external directors and the composition of our audit committee and compensation committee.

Accordingly, in August 2023, our shareholders approved the election of Prof. Benjamin Dekel and Assaf Itshayek as external directors (within the meaning of the Companies Law), each to serve for an initial three-year term, effective as of the closing of the private placement, which was consummated on September 7, 2023.

The Companies Law provides that a person may not serve as an external director if the person is a relative (as such term is defined in the Companies Law) of a controlling shareholder or if, on the date of the person's appointment or within the preceding two years, the person or his or her relatives (as such term is defined in the Companies Law), partners, employers or anyone to whom that person is subordinate (directly or indirectly), or entities under the person's control have or had any affiliation with the company, the controlling shareholder of the company or relative of a controlling shareholder, at the time of the appointment, or any entity that, as of the appointment date is, or at any time during the two years preceding that date was, controlled by the company or by the company's controlling shareholder (each an "Affiliated Party"). The term "affiliation" generally includes: an employment relationship; a business or professional relationship maintained on a regular basis (excluding insignificant relationships); control; and service as an office holder (excluding service as a director in a private company prior to the first offering of its shares to the public if such director was appointed as a director of the private company in order to serve as an outside director following the initial public offering). Notwithstanding the foregoing, a person may not serve as an external director if that person or that person's relative, partner, employer, a person to whom such person is subordinate (directly or indirectly) or any entity under the person's control has a business or professional relationship with any entity or person that has an affiliation with any Affiliated Party, even if such relationship is intermittent (excluding insignificant relationships). Additionally, any person who has received, during his or her tenure as an external director, direct or indirect compensation from the company for his or her role as a director, other than compensation permitted under the Companies Law and the regulations promulgated thereunder (including indemnification or exculpation, the company's commitment to indemnify or exculpate such person and insurance coverage), may not continue to serve as an external director.

No person may serve as an external director if the person's positions or other affairs create, or may create, a conflict of interest with that person's responsibilities as a director, or may otherwise interfere with such person's ability to serve as a director, or if the person is an employee of the Israel Securities Authority or of an Israeli stock exchange. If at the time an external director is appointed all current members of the board of directors, who are not the controlling shareholder or relatives of the controlling shareholder, are of the same gender, then the external director to be appointed must be of the other gender. In addition, a person who is a director of a company may not be elected as an external director of another company if, at that time, a director of the other company is acting as an external director of the first company.

An external director must meet certain professional qualifications or have financial and accounting expertise, as such terms are defined under regulations promulgated pursuant to the Companies Law. At least one external director must have financial and accounting expertise. The board of directors determines whether a director possesses financial and accounting expertise or professional qualifications. Our Board of Directors has determined that Assaf Itshayek has financial and accounting expertise and Prof. Benjamin Dekel has the requisite professional qualifications.

External directors are elected by shareholders by the affirmative vote of the holders of a majority of the ordinary shares represented at the meeting, in person or by proxy, entitled to vote and voting on the matter, provided that one of the following conditions is met: (i) the shares voting in favor of the election of the external director (excluding abstentions) include at least a majority of the shares voted by shareholders who are not controlling shareholders and shareholders who do not have a personal interest in such election (excluding a personal interest that is not related to a relationship with a controlling shareholder), or (ii) the total number of shares voted against the election by shareholders referred to in clause (i) does not exceed 2% of our outstanding voting rights.

Under Israeli law, the initial term of an external director of an Israeli public company is three years. An external director may be re-elected, subject to certain circumstances and conditions, to two additional terms of three years, and as a company whose shares are listed on the TASE and a foreign exchange, our external directors may be elected to additional terms of three years each, subject to conditions set out in regulations promulgated under the Companies Law.

An external director may be removed at a special general meeting of shareholders called by the board of directors by the same special majority of the shareholders required for his or her election (as detailed above) if he or she ceases to meet the statutory qualifications for appointment or if he or she violates his or her duty of loyalty to the company. An external director may also be removed by order of an Israeli court if the court finds that the external director is permanently unable to exercise his or her duties, has ceased to meet the statutory qualifications for his or her appointment or has violated his or her duty of loyalty to the company.

If the vacancy of an external directorship causes a company to have fewer than two external directors, the company's board of directors is required under the Companies Law to call a special general meeting of the company's shareholders as soon as possible to appoint such number of new external directors so that the company thereafter has two external directors.

Each committee authorized to exercise any of the powers of the board of directors is required to include at least one external director, and both the audit committee and compensation committee are required to include all of the external directors.

An external director is entitled to compensation as provided in regulations adopted under the Companies Law and is otherwise prohibited from receiving any other compensation, directly or indirectly, in connection with such service.

Audit Committee

We have an audit committee consisting of Ms. Lilach Payorski, an independent director under the Companies Law and Nasdaq Listing Rules, and our external directors, Assaf Itshayek and Prof. Benjamin Dekel. Mr. Assaf Itshayek serves as the chairman of the audit committee.

Under the Companies Law, publicly traded companies must establish an audit committee. The audit committee must consist of at least three members, and must include all the company's external directors, including one external director serving as chair of the audit committee; and the majority of the audit committee members must be "independent directors" (as such term is defined in the Companies Law). The chairman of the board of directors, directors employed by, or that provide services on a regular basis to, the company or to a controlling shareholder or a company controlled by a controlling shareholder, or a director whose main livelihood depends on a controlling shareholder, or any controlling shareholder and any relative of a controlling shareholder may not be a member of the audit committee. An audit committee may not approve an action or a transaction with an officer or director, a transaction in which an officer or director has a personal interest, a transaction with a controlling shareholder and certain other transactions specified in the Companies Law, unless at the time of approval two external directors are serving as members of the audit committee and at least one of the external directors was present at the meeting in which approval was granted.

Under the Exchange Act and Nasdaq listing requirements, 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. Our board of directors has affirmatively determined that each member of our audit committee qualifies as an "independent director" for purposes of serving on an audit committee under the Exchange Act and Nasdaq listing requirements. Our board of directors has determined that Lilach Payorski qualifies as an "audit committee financial expert," as defined in Item 407(d)(5) of Regulation S-K. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq.

Audit Committee Role

Our audit committee generally provides assistance to our board of directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting and internal control functions by reviewing the services of 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. Our audit committee also acts as a corporate governance compliance committee and oversees the implementation and amendment, from time to time, of our policies for compliance with Israeli and U.S. securities laws and applicable Nasdaq corporate governance requirements, including non-use of inside information, reporting requirements, our engagement with related parties, whistleblower complaints and protection, and is also responsible for the handling of any incidents that may arise in violation of our policies or applicable securities laws. Our board of directors has adopted an audit committee charter setting forth the specific responsibilities of the audit committee consistent with the Companies Law, and the rules and regulations of the SEC and the Nasdaq listing requirements, which include:

- oversight of our independent auditors and recommending the engagement, compensation or termination of engagement of our independent auditors to the board of directors or shareholders for their approval, as applicable, in accordance with the requirements of the Companies Law;
- pre-approval of audit and non-audit services to be provided by the independent auditors;
- reviewing and recommending to the board of directors approval of our quarterly and annual financial reports; and
- overseeing the implementation and amendment of our policies for compliance with Israeli and U.S. securities laws and applicable Nasdaq corporate governance requirements.

Additionally, under the Companies Law, the role of the audit committee includes: (1) determining whether there are delinquencies in the business management practices of our company, including in consultation with our internal auditor or our independent auditor, and making recommendations to the board of directors to improve such practices; (2) determining whether to approve certain related party transactions (including transactions in which an office holder has a personal interest) and whether any such transaction is an extraordinary or material transaction under the Companies Law; (3) determining whether a competitive process must be implemented for the approval of certain transactions with controlling shareholders or in which a controlling shareholder has a personal interest (whether or not the transaction is an extraordinary transaction), under the supervision of the audit committee or other party determined by the audit committee and in accordance with standards determined by the audit committee, or whether a different process determined by the audit committee should be implemented for the approval of such transactions; (4) determining the process for the approval of certain transactions with controlling shareholders that the audit committee has determined are not extraordinary transactions but are not immaterial transactions; (5) where the board of directors approves the work plan of the internal auditor, examining such work plan before its submission to the board of directors and proposing amendments thereto; (6) examining our internal controls and internal auditor's performance, including whether the internal auditor has sufficient resources and tools to dispose of its responsibilities; (7) examining the scope of our auditor's work and compensation and submitting its recommendation with respect thereto to the corporate body considering the appointment thereof (either the board of directors or the shareholders at the general meeting); and (8) establishing procedures for the handling of employees' complaints as to the management of our business and the protection to be provided to such employees.

Compensation Committee

We have a compensation committee consisting of Ms. Lilach Payorski, an independent director under the Companies Law and Nasdaq Listing Rules, and our external directors, Assaf Itshayek and Prof. Benjamin. Mr. Assaf Itshayek serves as the chairman of the compensation committee.

Under the Companies Law, publicly traded companies must establish a compensation committee, including an external director serving as chair of the compensation committee. The compensation committee must consist of at least three members and must include all of the company's external directors, who must form a majority of its members. The additional members of the compensation committee must satisfy the criteria for remuneration applicable to the external directors. The restrictions under the Companies Law regarding who may serve on the audit committee, as detailed above, apply to membership on the compensation committee.

Under Nasdaq listing requirements, we are required to maintain a compensation committee consisting of at least two members, each of whom is an "independent director" under the Nasdaq listing requirements. Our board of directors has affirmatively determined that each member of our compensation committee qualifies as an "independent director" under the Nasdaq listing requirements.

Compensation Committee Role

In accordance with the Companies Law, the roles of the compensation committee are, among others, as follows:

- recommending to the board of directors with respect to the approval of the compensation policy for office holders and, once every three years, regarding any extensions to a compensation policy that was adopted for a period of more than three years;
- reviewing the implementation of the compensation policy and periodically recommending to the board of directors with respect to any amendments or updates of the compensation policy;
- resolving whether or not to approve arrangements with respect to the terms of office and employment of office holders; and
- exempting, under certain circumstances, a transaction with our Chief Executive Officer from the approval of the general meeting of our shareholders.

We rely on the "foreign private issuer exemption" with respect to the Nasdaq requirement to have a formal charter for the compensation committee.

Strategy Committee

Our strategy committee currently consists of Ms. Lilach Asher-Topilsky, Mr. David Tsur and Mr. Uri Botzer. Ms. Lilach Asher-Topilsky serves as the chair of the strategy committee.

The roles of our strategy committee are (among others): (1) reviewing periodically and making recommendations to the board of directors with respect to our strategic plan and overall strategy, our research and development plan, annual work plan and budget, strategy with respect to mergers and acquisitions, and any strategic initiatives identified our board of directors or management from time to time, including the exit from existing lines of business and entry into newlines of business, joint ventures, acquisitions, investments, dispositions of business and assets and business expansions; (2) guiding management in the development of our strategy, including reviewing and discussing with management our strategic direction and initiatives and the risks and opportunities associated with our strategy; (3) reviewing with management the process for development, approval and modification of the strategy and strategic plan; (4) assisting management with identifying key issues, options and external developments impacting our strategy; (5) reviewing management's progress in implementing our global strategy; and (6) ensuring the board of directors is regularly apprised of the progress with respect to implementation of any approved strategy.

Internal Auditor

Under the Companies Law, the board of directors of a public company must appoint an internal auditor recommended by the audit committee. The role of the internal auditor is, among other things, to examine whether a company's actions comply with applicable law and orderly business procedure. Under the Companies Law, the internal auditor may not be an "interested party" or an office holder, or a relative of an interested party or of an office holder, nor may the internal auditor be the company's independent accounting firm or anyone acting on its behalf. An "interested party" is defined in the Companies Law as (i) a holder of 5% or more of the company's outstanding shares or voting rights, (ii) any person or entity (or relative of such person) who has the right to designate one or more directors or to designate the chief executive officer of the company, or (iii) any person who serves as a director or as a chief executive officer of the company. Tali Yaron of Brightman Almagor Zohar & Co. (a Firm in the Deloitte Global Network) serves as our internal auditor.

Fiduciary Duties and Approval of Specified Related Party Transactions under Israeli Law

Fiduciary Duties of Office Holders

The Companies Law codifies the fiduciary duties that office holders owe to a company. Each person listed in the table under "Management — 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 care includes, among other things, a duty to use reasonable means, in light of the circumstances, to obtain:

- information on the advisability of a given action brought for his or her approval or performed by the director in his or her capacity as a director; and
- all other important information pertaining to such action.

The duty of loyalty requires an office holder to act in good faith and for the benefit of the company, and includes, among other things, the duty to:

- refrain from any act involving a conflict of interests 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 business of 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.

We may approve an act specified above which would otherwise constitute a breach of the office holder's duty of loyalty provided that the office holder acted in good faith, the act or its approval does not harm the company and the office holder discloses his or her personal interest a sufficient amount of time before the date for discussion of approval of such act.

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

The Companies Law requires that an office holder promptly disclose to the company any "personal interest" that he or she may have, and all related material information or documents relating to any existing or proposed transaction by the company. A "personal interest" is defined under the Companies Law as the personal interest of a person in an action or in a transaction of the company, including the personal interest of such person's relative or of any other corporate entity in which such person and/or such person's relative is a director, general manager or chief executive officer, a holder of 5% or more of the outstanding shares or voting rights, or has the right to appoint at least one director or the general manager, but excluding a personal interest arising solely from ownership of shares in the company. A personal interest includes the personal interest of a person for whom the office holder holds a voting proxy and the personal interest of a person voting as a proxy, even when the person granting such proxy has no personal interest. An interested office holder's disclosure must be made promptly and no later than the first meeting of the board of directors at which the transaction is considered. An office holder is not obliged to disclose such information if the personal interest of the office holder derives solely from the personal interest of his or her relative in a transaction that is not considered as an "extraordinary transaction."

An "extraordinary transaction" is defined under the Companies Law 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 is likely to have a material impact on the company's profitability, assets or liabilities.

Under the Companies Law, unless the articles of association of a company provide otherwise, a transaction with an office holder or with a third party in which the office holder has a personal interest, and which is not an extraordinary transaction, requires approval by the board of directors. Our articles of association do not provide for a different method of approval. If the transaction is an extraordinary transaction with an office holder or third party in which the office holder has a personal interest, then audit committee approval is required prior to approval by the board of directors. The audit committee determines whether any such transaction is an "extraordinary transaction" (within the meaning of the Companies Law). For the approval of compensation arrangements with directors and officers who are controlling shareholders, see "— Disclosures of Personal Interests of a Controlling Shareholder and Approval of Certain Transactions," for the approval of compensation arrangements with directors, see "— Compensation of Directors" and for the approval of compensation arrangements with office holders who are not directors, see "— Compensation of Executive Officers."

Subject to certain exceptions, any person who has a personal interest in the approval of a transaction that is brought before a meeting of the board of directors or the audit committee may not be present at the meeting, unless such person is an office holder and invited by the chairman of the board of directors or of the audit committee, as applicable, to present the matter being considered, and may not vote on the matter. In addition, a director who has a personal interest in the approval of a transaction may be present at the meeting and vote on the matter if a majority of the directors or members of the audit committee, as applicable, have a personal interest in the transaction. In such case, shareholder approval is also required.

Disclosure of Personal Interests of a Controlling Shareholder and Approval of Certain Transactions

Pursuant to the Companies Law, the disclosure requirements regarding personal interests that apply to office holders also apply to a controlling shareholder of a public company. For this purpose, a controlling shareholder is a shareholder who has the ability to direct the activities of a company, including a shareholder who owns 25% or more of the voting rights if no other shareholder owns more than 50% of the voting rights. Two or more shareholders with a personal interest in the approval of the same transaction are deemed to be one shareholder.

Extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, the terms of services provided by a controlling shareholder or his or her relative, directly or indirectly (including through a corporation controlled by a controlling shareholder), the terms of employment of a controlling shareholder or his or her relative who is employed by the company and who is not an office holder and the terms of service and employment, including exculpation, indemnification or insurance, of a controlling shareholder or his or her relative who is an office holder, require the approval of each of the audit committee or the compensation committee with respect to terms of service and employment by the company as an office holder, employee or service provider, the board of directors and the shareholders, in that order. In addition, the shareholder approval must fulfill one of the following requirements:

- at least a majority of the shares held by shareholders who have no personal interest in the transaction and who are present and voting at the meeting on the matter are voted in favor of approving the transaction, excluding abstentions; or
- the shares voted against the transaction by shareholders who have no personal interest in the transaction who are present and voting at the meeting represent no more than 2% of the voting rights in the company.

Each shareholder voting on the approval of an extraordinary transaction with a controlling shareholder must inform the company prior to voting whether or not he or she has a personal interest in the approval of the transaction, otherwise, the shareholder is not eligible to vote on the proposal and his or her vote will not be counted for purposes of the proposal.

Any extraordinary transaction with a controlling shareholder or in which a controlling shareholder has a personal interest with a term of more than three years requires approval every three years, unless the audit committee determines that the duration of the transaction is reasonable given the circumstances related thereto.

Pursuant to regulations promulgated under the Companies Law, certain transactions with a controlling shareholder or his or her relative, or with directors, relating to terms of service or employment, that would otherwise require approval of the shareholders may be exempt from shareholder approval upon certain determinations of the audit committee and board of directors.

Duties of Shareholders

Under the Companies Law, a shareholder has a duty to refrain from abusing his or her power in the company and to act in good faith and in a customary manner in exercising its rights and performing its obligations to the company and other shareholders, including, among other things, when voting at meetings of shareholders on the following matters:

- an amendment to the company's articles of association;
- an increase in the company's authorized share capital;
- a merger; and
- the approval of related party transactions and acts of office holders that require shareholder approval.

A shareholder also has a general duty to refrain from discriminating against other shareholders.

In addition, certain shareholders have a duty to act with fairness towards the company. These shareholders include any controlling shareholder, any shareholder who knows that his or her vote can determine the outcome of a shareholder vote, and any shareholder that, under a company's articles of association, has the power to appoint or prevent the appointment of an office holder or has another power with respect to the company. The Companies Law does not define the substance of this duty 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.

Approval of Significant Private Placements

Under the Companies Law, a significant private placement of securities requires approval by the board of directors and the shareholders by a simple majority. A private placement is considered a significant private placement if it will cause a person to become a controlling shareholder or if all of the following conditions are met:

- the securities issued amount to 20% or more of the company's outstanding voting rights before the issuance;
- some or all of the consideration is other than cash or listed securities or the transaction is not on market terms; and
- the transaction will increase the relative holdings of a shareholder who holds 5% or more of the company's outstanding share capital or voting rights or that will cause any person to become, as a result of the issuance, a holder of more than 5% of the company's outstanding share capital or voting rights.

D. Employees

Set forth below is a chart showing the number of people we employed at the times indicated:

	As of December 31,		
	2023	**2022**	**2021**
Total Employees	**378**	**379**	**366**
Located in Israel	347	360	355
Located in the United States	29	17	11
Located in Other Countries	2	2	-
In Research and Development	38	37	36
In General and Administrative	57	52	35
In Operations	249	259	274
In Sales and Marketing	34	31	21

We signed a collective bargaining agreement with the Histadrut (General Federation of Labor in Israel) and the employees' committee established by our employees at our Beit Kama facility in December 2013, which expired in December 2017. In November 2018, we signed a further collective bargaining agreement with the employees' committee and the Histadrut, which expired in December 2021. In July 2022, we signed a new collective agreement with the employee's committee and the Histadrut; while the agreement will be effective through the end of 2029, certain economic terms may be renegotiated by the parties following the four-year anniversary of the agreement. The collective bargaining agreement governs certain aspects of our employee-employer relations, such as: firing procedures, annual salary raise, and eligibility for certain compensation terms and welfare. Approximately 180 of our employees, all of whom are located at our Beit Kama facility, currently work under the collective bargaining agreement signed in July 2022. We have experienced labor disputes and work stoppages in the past at our Beit Kama facility. For example, on March 3, 2022, during the course our negotiations with the Histadrut and the employees' committee on the renewal of the collective bargaining agreement, the employee's committee declared a labor dispute, and on April 26, 2022, a strike was initiated by the employees' committee, which continued until signed agreement was signed in July 2022, at which time the unionized employees returned to work at the Beit Kama facility. In addition, in December 2020, during the course of our negotiations with the Histadrut and the employees' committee on severance remuneration for employees who may be laid-off as part of the workforce down-sizing as a result of the transfer of GLASSIA manufacturing to Takeda, the employee's committee declared a labor dispute, which was subsequently concluded during February 2021 following the execution of a special collective bargaining agreement governing such severance terms. In March 2023, we entered into an additional special collective bargaining agreement with the employees' committee and the Histadtrut governing severance remuneration terms for employees who may be laid-off in connection with the potential staff reductions, when needed, in order to adjust to lower plant utilization.

In regard to our Israeli employees, Israeli labor laws 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 the applicable Israeli legal requirements.

Extension orders issued by the Ministry of Labor, Social Affairs, and Social Services apply to us and affect matters such as cost of living adjustments to payroll, length of working hours and week, recuperation pay, travel expenses, and pension rights.

E. Share Ownership

The following table sets forth information with respect to the beneficial ownership of our ordinary shares by each of our directors and executive officers and all of current directors and executive officers as a group.

The percentage of beneficial ownership of our ordinary shares is based on 57,479,528 ordinary shares outstanding as of March 1, 2024. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting power or investment power with respect to securities. All ordinary shares subject to options exercisable into ordinary shares and restricted share units that will become vested, as applicable, within 60 days of the date of the table are deemed to be outstanding and beneficially owned by the shareholder holding such options and restricted share units for the purpose of computing the number of shares beneficially owned by such shareholder. They are not, however, deemed to be outstanding and beneficially owned for the purpose of computing the percentage ownership of any other shareholder.

	Ordinary Shares Beneficially Owned	
Name	**Number**	**Percentage**
Executive Officers		
Amir London (1)	359,875	*
Chaime Orlev (2)	91,533	*
Eran Nir (3)	85,798	*
Yael Brenner (4)	55,066	*
Hanni Neheman (5)	43,667	*
Nir Livneh (6)	10,000	*
Orit Pinchuk (7)	72,533	*
Liron Reshef (8)	10,000	*
Jon Knight (9)	30,000	*
Shavit Beladev (10)	43,668	*
Boris Gorelik (11)	26,250	*
Directors		
Lilach Asher-Topilsky (12)	34,000	*
Uri Botzer (13)	7,500	*
Ishay Davidi (14)	22,118,287	38.46%
Prof. Benjamin Dekel (15)	-	-
Karnit Goldwasser (16)	34,000	*
Assaf Itshayek (17)	-	-
Lilach Payorski (18)	7,500	*
Leon Recanati (19)	3,542,886	6.16%
David Tsur (20)	661,929	1.15%
Directors and executive officers as a group (20 persons) (21)	27,234,492	47.21%

* Less than 1% of our ordinary shares.

(1) Includes (i) 60,000 ordinary shares (ii) 1,875 restricted share units that vest within 60 days of the date of the table and (iii) options to purchase 298,000 ordinary shares exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 19.67 (or $5.39) per share, which expire between May 30,2024 and June 22, 2029. Does not include unvested options to purchase 300,000 ordinary shares that are not exercisable within 60 days of the date of the table.

(2) Includes (i) 11,633 ordinary shares, and (ii) options to purchase 79,900 ordinary shares exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 19.39 (or $5.32) per share, which expire between May 12, 2024 and November 28, 2029. Does not include unvested options to purchase 135,000 ordinary shares units that are not exercisable within 60 days of the date of the table.

(3) Includes (i) 10,398 ordinary shares, and (ii) options to purchase 75,400 ordinary shares exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 19.675 (or $5.39) per share, which expire between December 27, 2024 and August 28, 2028. Does not include unvested options to purchase 45,000 ordinary shares that are not exercisable within 60 days of the date of the table.

(4) Includes (i) 6,266 ordinary shares, and (ii) options to purchase 48,800 ordinary shares exercisable within 60 days of the date of the table, at exercise price of NIS 19.78 (or $5.42) per share, which expire between December 27, 2024 and August 28, 2028. Does not include unvested options to purchase 30,000 ordinary shares that are not exercisable within 60 days of the date of the table.

(5) Includes (i) 3,417 ordinary shares, and (ii) options to purchase 40,250 ordinary shares exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 19.40 (or $5.32) per share, which expire between December 27, 2024 and August 28, 2028. Does not include unvested options to purchase 30,000 ordinary shares that are not exercisable within 60 days of the date of the table.

(6) Subject to options to purchase 10,000 ordinary shares exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 17.67 (or $4.85) per share, which expire on October 23, 2029. Does not include unvested options to purchase 30,000 ordinary shares that are not exercisable within 60 days of the date of the table.

(7) Includes (i) 12,133 ordinary shares, and (ii) options to purchase 60,400 ordinary shares exercisable within days of the date of the table, at an exercise price of NIS 19.78 (or $5.42) per share, which expire between December 27, 2024 and August 28, 2028. Does not include unvested options to purchase 30,0000 ordinary shares that are not exercisable within 60 days of the date of the table.

(8) Includes options to purchase 10,000 ordinary shares exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 16.75 (or $4.59) per share, which expires at September 02, 2029. Does not include unvested options to purchase 30,000 ordinary shares that are not exercisable within 60 days of the date of the table.

(9) Subject to options to purchase 30,000 ordinary shares exercisable within 60 days of the date of the table, at an exercise price of NIS 20.58 (or $6.5) per share, which expire on September 9, 2028. Does not include unvested options to purchase 30,000 ordinary shares that are not exercisable within 60 days of the date of the table.

(10) Includes (i) 3,418 ordinary shares, and (ii) options to purchase 40,250 ordinary shares exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 19.40 (or $5.32) per share, which expire between December 27, 2024 and August 28, 2028. Does not include unvested options to purchase 30,000 ordinary shares that are not exercisable within 60 days of the date of the table.

(11) Includes options to purchase 26,250 ordinary shares exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 22.75 (or $4.59) per share, which expire between February 11, 2027 and January 16, 2029. Does not include unvested options to purchase 48,750 ordinary shares units that are not exercisable or do no vest, as applicable, within 60 days of the date of the table.

(12) Subject to options to purchase 34,000 ordinary shares exercisable within 60 days of the date of the table, at an exercise price of NIS 22.71 (or $6.23) per share, which expire between September 25, 2026 and June 22, 2029. Does not include unvested options to purchase 22,500 ordinary shares that are not exercisable within 60 days of the date of the table.

(13) Subject to options to purchase 7,500 ordinary shares exercisable within 60 days of the date of the table, at an exercise price of NIS 17.35 (or $4.76) per share, which expire on June 22, 2029. Does not include unvested options to purchase 22,500 ordinary shares that are not exercisable within 60 days of the date of the table.

(14) Includes (i) 22,084,287 shares indirectly beneficially owned through the FIMI 6 Funds and FIMI 7 Funds. and (ii) 34,000 ordinary shares subject to options held directly held by Mr. Ishay Davidi that are currently exercisable or exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 22.71 (or $6.23) per share, which expire between September 25, 2026 and June 22, 2029. Does not include unvested options to purchase 22,500 ordinary shares held by Mr. Ishay Davidi that are not exercisable within 60 days of the date of the table.

(15) Does not include ordinary shares subject to unvested options to purchase 16,000 ordinary shares that are not exercisable within 60 days of the date of the table.

(16) Subject to options to purchase 34,000 ordinary shares that are currently exercisable or exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 22.71 (or $6.23) per share, which expire between September 25, 2026, and June 22, 2029. Does not include unvested options to purchase 22,500 ordinary shares that are not exercisable within 60 days of the date of the table.

(17) Does not include ordinary shares subject to unvested options to purchase 16,000 ordinary shares that are not exercisable within 60 days of the date of the table.

(18) Subject to options to purchase 7,500 ordinary shares exercisable within 60 days of the date of the table, at an exercise price of NIS 19.36 (or $5.31) per share, which expire on June 22, 2029. Does not include unvested options to purchase 22,500 ordinary shares that are not exercisable within 60 days of the date of the table.

(19) Mr. Recanati (i) directly holds 631,145 ordinary shares and (ii) beneficially owns 1,511,406 ordinary shares through Gov Financial Holdings Ltd. ("Gov") and 1,346,335 ordinary shares through Insight Capital Ltd. ("Insight"), both of which are wholly owned by Mr. Recanati. In addition, includes options to purchase 54,000 ordinary shares directly held by Mr. Recanati that are exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 22.26 (or $6.11) per share, which expire between May 30, 2024 and June 22, 2029. Does not include ordinary shares subject to unvested options to purchase 22,500 ordinary shares that are not exercisable within 60 days of the date of the table.

(20) Mr. David Tsur directly holds 607,929 ordinary shares. In addition, includes options to purchase 54,000 ordinary shares directly held by Mr. Tsur that are currently exercisable or exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 22.27 (or $6.11) per share, which expire between May 30, 2024 and June 22, 2029. Does not include unvested options to purchase 22,500 ordinary shares that are not exercisable within 60 days of the date of the table.

(21) See footnotes (1)-(20) for certain information regarding beneficial ownership.

Equity Compensation Plan

In July 2011, we adopted our 2011 Israeli Share Option Plan and in September 2016, we amended and renamed it as the 2011 Israeli Share Award Plan (the "2011 Plan"). The 2011 Plan expired in July 2021 and in August 2021, we extended the 2011 Plan by an additional ten years, until August 9, 2031, and adopted a few additional amendments to the 2011 Plan and the 2011 Plan was further amended in October 2022. References below to the "2011 Plan" refer to the 2011 Plan as amended in August 2021 and October 2022. Under the 2011 Plan, we are authorized to grant options and restricted share units to directors, officers, employees, consultants and service providers of our company and subsidiaries. The 2011 Plan is intended to enhance our ability to attract and retain desirable individuals by increasing their ownership interests in us. The 2011 Plan is designed to reflect the provisions of the Israeli Income Tax Ordinance [New Version], 1961 (the ("Israeli Income Tax Ordinance"), which affords certain tax advantages to Israeli employees, officers and directors that are granted equity awards (including options and restricted stock units) in accordance with its terms. The 2011 Plan may be administered by our board of directors either directly or upon the recommendation of the compensation committee.

In February 2022, the Board of Directors adopted the U.S. Taxpayer Appendix to the 2011 Plan (the "US Appendix"), which provides for the grant of options and restricted shares to persons who are subject to U.S. federal income tax. The Appendix provides for the grant to U.S. employees of options that qualify as incentive stock options ("ISOs") under the U.S. Internal Revenue Code of 1986, as amended. The aggregate maximum number of ordinary shares that may be issued upon the exercise of ISOs granted under the 2011 Plan is 500,000. The grant of ISO's was subject to the approval of the Appendix by our shareholders within 12 months of its approval by our Board of Directors. The US Appendix was approved by our shareholders at the annual general meeting held in December 2022.

We have granted options to our employees, officers and directors under the 2011 Plan. Each option granted under the 2011 Plan entitles the grantee to purchase one of our ordinary shares. In general, the exercise price of options granted to directors and officers under the 2011 Plan prior to January 1, 2020, is generally equal to the higher of (i) the average closing price of our ordinary shares on the TASE during the 30-TASE trading days immediately prior to board approval of the grant of such options plus 5%; and (ii) the closing price of our ordinary shares on the TASE on the date of the approval of the grant of options. The exercise price of options granted to directors and officers under the 2011 Plan following January 1, 2020 is generally equal to the higher of (i) the average closing price of our ordinary shares on the TASE during the 30-TASE trading days immediately prior to board approval of the grant of such options; and (ii) the closing price of our ordinary shares on the TASE on the date of the approval of the grant of options. Options granted under the 2011 Plan are exercised by way of net exercise and accordingly, the grantee is not required to pay the exercise price when exercising the options and instead, receives, upon exercise and sale of such number of ordinary shares, an amount which is equal to the difference between the total market value of the ordinary shares on the date of exercise and sale underlying the exercised options and the total exercise price for such options. The actual number of shares issued pursuant to the net exercise of the options is equal to the number of shares subject to the option less the number of shares tendered back to the company to pay the exercise price.

The options granted under the 2011 Plan prior to January 1, 2020 generally vest during a four-year period following the date of the grant in 13 installments: 25% of the options vest on the first anniversary of the grant date and 6.25% of the remaining options vest at the end of each quarter thereafter. Options granted under the 2011 Plan following January 1, 2020 generally vest in four equal installments, 25% each on each of the four anniversaries of the date of grant. Options granted under the 2011 Plan are generally exercisable for 6.5 years following the date of grant and all unexercised options will expire immediately thereafter. Options that have vested prior to the end of a grantee's employment or services agreement with us may generally be exercised within 90 days from the end of such grantee's employment or services with us, unless such relationship was terminated for cause. Options which are not exercised during such 90-day period expire at the end of the period, unless upon termination of such 90-day period there is an ongoing black-out period during which time the options may not be exercised, in which case our Chief Executive Officer or Chief Financial Officer is entitled to extend the exercise period for specified limited periods. Options that have not vested on the date of the end of a grantee's employment or services agreement with us, and, in the event of termination of employment or services for cause, all unexercised options (whether vested or not), expire immediately upon termination.

We have also granted restricted share units to our officers. The restricted share units awarded under the 2011 Plan generally vest over a period of four years in 13 installments: 25% of the restricted share units vest on the first anniversary of the grant date and 6.25% of the remaining restricted share units vest at the end of each quarter thereafter.

In the event of certain transactions, such as our being acquired, or a merger or reorganization or a sale of all or substantially all of our shares or assets, the board or compensation committee may take one of the following actions: (i) provide that awards then outstanding under the 2011 Plan shall be assumed or substituted for shares or other securities of the surviving or acquiring entity, under such terms and conditions determined by the board or the compensation committee; (ii) provide for the acceleration of vesting of all a part of any awards then outstanding under the 2011 Plan, under such terms and conditions as the Board or the compensation committee shall determine; or (iii) provide for the cancellation of any award without any consideration, if the fair market value per share on the date of the transaction does not exceed the purchase price of any such award or if such award would not otherwise be exercisable or vested, even in the event that the fair market value per share on the date of the transaction, exceeds the purchase price of any such award. The board or the compensation committee may determine that the terms of certain awards under the 2011 Plan include a provision that their vesting schedules will be accelerated such that they will be exercisable prior to the closing of such a transaction, if the awards are not assumed or substituted by the successor company.

Options and restricted share units granted to our employees and Israeli directors under the 2011 Plan were granted pursuant to the provisions of Section 102 of the Israeli Income Tax Ordinance, under the capital gains alternative. In order to comply with the capital gains alternative, all such options and restricted share units under the 2011 Plan are granted or issued to a trustee and are to be held by the trustee for at least two years from the date of grant. Under the capital gains alternative, we are not allowed an Israeli tax deduction for the grant of the options or issuance of the shares issuable thereunder.

As of December 31, 2023, an aggregate of 786,573 ordinary shares were reserved for future issuance under the 2011 Plan (subject to certain adjustments specified in the 2011 Plan), and options to purchase 3,269,981 ordinary shares were outstanding under the 2011 Plan, of which options to purchase 1,469,084 ordinary shares were vested as of such date, and 1,875 restricted share units were outstanding under the 2011 Plan. Any ordinary shares underlying options that expire prior to exercise or restricted share units that are forfeited under the 2011 Plan will become again available for issuance under the 2011 Plan. See Note 27 to our consolidated financial statements included in this Annual Report for information regarding awards subsequent to December 31, 2023.

F. Disclosure of a Registrant's Action to Recover Erroneously Awarded Compensation

There was no erroneously awarded compensation that was required to be recovered pursuant to the Kamada Ltd. Recoupment Policy during the fiscal year ended December 31, 2023.

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table sets forth information with respect to the beneficial ownership of our ordinary shares by each person known to us to own beneficially more than 5% of our ordinary shares.

The percentage of beneficial ownership of our ordinary shares is based on 57,479,528 ordinary shares outstanding as of March 1, 2024. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting power or investment power with respect to securities. All ordinary shares subject to options exercisable into ordinary shares within 60 days of the date of the table are deemed to be outstanding and beneficially owned by the shareholder holding such options for the purpose of computing the number of shares beneficially owned by such shareholder. Such shares are also deemed outstanding for purposes of computing the percentage ownership of the person holding the options. They are not, however, deemed to be outstanding and beneficially owned for the purpose of computing the percentage ownership of any other shareholder.

Except as described in the footnotes below, we believe each shareholder has voting and investment power with respect to the ordinary shares indicated in the table as beneficially owned.

Name	Number	Percentage
FIMI Funds(1)	22,084,287	38.42%
The Phoenix Holdings Ltd.(2)	4,314,270	7.51%
Leon Recanati(3)	3,542,886	6.16%

(1) Based solely upon, and qualified in its entirety with reference to, Amendment No. 3 to Schedule 13D filed with the SEC on September 7, 2023. According to the Statement, (A) (i) includes 4,421,909 shares directly owned by FIMI Opportunity Fund 6, L.P. and 5,030,799 shares directly owned by FIMI Israel Opportunity Fund 6, Limited Partnership (together, the "FIMI 6 Funds") and (ii) the 9,452,708 ordinary shares held by the FIMI 6 Funds are indirectly beneficially owned by FIMI 6 2016 Ltd. ("FIMI 6"), which serves as the managing general partner of the FIMI 6 Funds, and Or Adiv Ltd., a company controlled by Mr. Ishay Davidi, which controls FIMI 6; (B) (i) includes 4,911,158 shares directly owned by FIMI Opportunity 7, L.P. and 7,720,421 shares directly owned by FIMI Israel Opportunity Fund 7, Limited Partnership (together, the "FIMI 7 Funds") and (ii) the 12,631,579 ordinary shares held by the FIMI 7 Funds are indirectly beneficially owned by FIMI 7 2016 Ltd. ("FIMI 7"), which serves as the managing general partner of the FIMI 7 Funds, and O.D.N Seven Investments Ltd., a company controlled by Mr. Ishay Davidi, which controls FIMI 7; and (C) the 22,084,287 ordinary shares held by the FIMI 6 Funds and the FIMI 7 Funds are indirectly beneficially owned by Mr. Ishay Davidi. Information included in this footnote does not include 34,000 ordinary shares subject to options held directly by Mr. Ishay Davidi that are currently exercisable or exercisable within 60 days of the date of the table See Footnote (14) to the table under "Item 6. Directors, Senior Management and Employees — Share Ownership."

(2) Based solely upon, and qualified in its entirety with reference to, Amendment No. 16 to Schedule 13G filed with the SEC on February 12, 2024, reporting its holdings as of December 31, 2023. According to the Schedule 13G/A, the securities are beneficially owned by various direct or indirect, majority or wholly-owned subsidiaries of the Phoenix Holdings Ltd., each of which operates under independent management and makes its own independent voting and investment decisions.

(3) Mr. Recanati (i) directly holds 631,145 ordinary shares and (ii) beneficially owns 1,511,406 ordinary shares through Gov and 1,346,335 ordinary shares through Insight, both of which are wholly owned by Mr. Recanati. In addition, includes options to purchase 54,000 ordinary shares directly held by Mr. Recanati that are exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 22.26 (or $6.11) per share, which expire between May 30, 2024 and June 22, 2029. Does not include ordinary shares subject to unvested options to purchase 22,500 ordinary shares that are not exercisable within 60 days of the date of the table.

To our knowledge, based on information provided to us by our transfer agent in the United States, as of March 4, 2024, we had one shareholder of record registered with an address in the United States, holding approximately 17.84% of our outstanding ordinary shares. Such number is not representative of the portion of our shares held in the United States nor is it representative of the number of beneficial holders residing in the United States, since such ordinary shares were held of record by one U.S. nominee company, CEDE & Co.

To our knowledge, other than as disclosed in the table above, our other filings with the SEC and this Annual Report, there has been no significant change in the percentage ownership held by any major shareholder since January 1, 2021.

None of our shareholders has different voting rights from other shareholders. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

B. Related Party Transactions

Tuteur S.A.C.I.F.I.A.

Tuteur is a company organized under the laws of Argentina and was formerly controlled by Mr. Ralf Hahn, the former Chairman of our board of directors. Mr. Ralf Hahn's son, Mr. Jonathan Hahn, currently the President and a director of Tuteur, served as a director of our company from March 2010 until November 2023.

In August 2011, we entered into a distribution agreement with Tuteur that amended and restated a distribution agreement we entered into in November 2001, as amended on August 19, 2014, January 25, 2017, and January 21, 2019, under which Tuteur acted as the exclusive distributor of GLASSIA and KAMRHO(D) in Argentina, Paraguay and Bolivia. The distribution agreement, as amended, expired on December 31, 2019, and pending the execution of a new distribution agreement, the parties continued to act in accordance with the expired distribution agreement.

In May 2020, we entered into a new distribution agreement with Tuteur, which supersedes the former agreement in its entirety, pursuant to which Tuteur serves as the exclusive distributor of GLASSIA and KAMRHO(D) in Argentina, Paraguay, Bolivia and Uruguay. Under the new distribution agreement, Tuteur is responsible, at its own expense, for obtaining marketing authorization and/or registration for each of the products in the foregoing territories that is not already approved and registered. If Tuteur fails to register any product in any territory within 12 months after receipt of our approval of all relevant documents, we shall be entitled to terminate the agreement with respect to such product or terminate the exclusivity granted to Tuteur with respect to such product. The agreement includes minimum annual purchase commitments by Tuteur, with respect to sales of any products in territories where registration has been completed, commencing as of the effective date of the agreement, and with respect to sale of any products in the other territories, commencing the first year following the registration of any such product in the applicable territory; and the parties agreed to negotiate in good faith the minimum quantities to be purchased by Tuteur in each following marketing year. If Tuteur fails to purchase and pay for the minimum quantity for any product in any marketing year, we are entitled to (i) terminate the agreement on a product-by-product basis and/or (ii) terminate the exclusivity and/or narrow the scope of the territories, if applicable, on a product-by-product basis. The price per product per territory payable by Tuteur pursuant to the agreement will be the higher of 50% of such product's net price sold by Tuteur in the territory or a minimum supply price as defined in the agreement.

In addition, Tuteur has undertaken to issue a guarantee (from a U.S., Israeli or a western Europe bank) for every new order of product, in the value of each order, which must be provided prior to the shipment of the product and extended through the complete payment of the amount due on any such order or shipment; such guarantee may not be required to the extent we are able to obtain adequate credit insurance covering the value of each order through its complete payment. We retain ownership of all relevant intellectual property in the products. The agreement is in effect for a period of five years, and thereafter shall automatically renew for additional periods of one year each, unless either party notifies the other party of its desire to terminate the agreement by prior written notice of at least 12 months before the expiration of any of the additional periods. We are entitled to terminate the agreement with respect to all or certain territories in the event of a change of control of Tuteur, its failure to register the products and obtain all marketing approvals within the period set forth above, its failure to purchase and pay for the minimum quantities for two consecutive years (provided that Tuteur will be obligated, during the second marketing year, to purchase the minimum quantity for the preceding marketing year on a product-by-product basis) or if Tuteur discontinues selling the products, after completing registration and obtaining required approvals, for longer than 45 days or 90 days or more in the event such discontinuation is caused due to a force majeure event. The agreement includes a mutual indemnification undertaking, standard confidentiality obligations and obligations of Tuteur to comply with anti-corruption and privacy laws. The agreement includes a non-compete undertaking of Tuteur during the term of the agreement and for a period of 12 months thereunder (other than in the event the agreement is terminated for cause by Tuteur due to our breach of the agreement).

On July 4, 2022, we and Tuteur entered into a supplemental letter agreement to the distribution agreement, pursuant to which Tuteur undertook to be responsible for an investigator-initiated targeted screening program for AATD in Uruguay in patients diagnosed with obtrusive pulmonary disease, with the purpose of identifying patients suitable for treatment with GLASSIA, to be conducted at Sociedad Uruguaya de Neumologia, Montevideo, Uruguay. We undertook to support the funding of the study up to $30,000, inclusive of all applicable taxes. Tuteur undertook to provide us all collected data, information, results and reports generated or derived as a result of the study, and to obtain in advance all necessary approvals for the study. According to the terms of the agreement, we shall not be responsible for or bear any liability arising from or in connection with the study.

In September 2022, following a decrease in the market price of KAMRHO(D) in Argentina mainly due to the impact of the COVID-19 pandemic and recent changes to treatment protocols that reduced overall consumption of the product, the Board of Directors approved the reduction of the minimum supply price (as defined in the distribution agreement) of the product in Argentina and Paraguay for the 2022 supplies. In February 2023, we and Tuteur entered into an amendment to the distribution agreement, pursuant to which KAMRHO(D)'s price for the territories of Argentina and Paraguay payable by Tuteur pursuant to the agreement will be the higher of 60% of KAMRHO(D)'s net price sold by Tuteur in these territories or a minimum supply price (as defined in the amendment to the distribution agreement).

In March 2023, the Board of Directors approved a one-time amendment to the payment terms under the distribution agreement with respect to two shipments of GLASSIA and KAMRHO(D) to be supplied to Tuteur by the end of the first quarter of 2023. In June 2023, due to continued political and economic changes and related mandates imposed by the Argentinian government, the Board of Directors approved further amendments to the distribution agreement, pursuant to which Tuteur may issue a bank guarantee from an Argentinian bank against improved payment terms and supply price.

In January 2024, following additional mandates imposed by the Argentinian government, we and Tuteur entered into an amendment to the distribution agreement, pursuant to which, so long as Tuteur does not undergo a "Change of Control" or "Management Change" (as such terms are defined in the amendment), Tuteur will not be required to provide a bank guarantee for orders shipped from December 1, 2023 and onwards, if the total outstanding amount due from Tuteur to us does not exceed $1.5 million at any time; provided that such a bank guarantee will be required for any shipment of product that, if shipped, would result in the total outstanding amount due by Tuteur to us to exceed such amount.

Indemnification Agreements

We have entered into indemnification and exculpation agreements with each of our current officers and directors, exculpating them from a breach of their duty of care to us to the fullest extent permitted by the Companies Law (provided that we may not exculpate an office holder for an action or transaction in which a controlling shareholder or any other office holder (including an office holder who is not the office holder we have undertaken to exculpate) has a personal interest (within the meaning of the Companies Law)) and undertaking to indemnify them to the fullest extent permitted by the Companies Law (other than indemnification for litigation expenses in connection with a monetary sanction), including with respect to liabilities resulting from our initial public offering in the United States, to the extent such liabilities are not covered by insurance. See "Item 6. Directors, Senior Management and Employees — Exculpation, Insurance and Indemnification of Office Holders."

Employment Agreements

We have entered into employment agreements with our executive officers and key employees, which are terminable by either party for any reason. The employment agreements contain standard provisions, including assignment of invention provisions and non-competition clauses. See "Item 6. Directors, Senior Management and Employees — Employment Agreements with Executive Officers."

Shareholders' Agreement

Under a shareholders' agreement entered into on March 4, 2013, the Recanati Group, on the one hand, and the Damar Group, on the other hand, have each agreed to vote the ordinary shares beneficially owned by them in favor of the election of director nominees designated by the other group as follows: (i) three director nominees, so long as the other group beneficially owns at least 7.5% of our outstanding share capital, (ii) two director nominees, so long as the other group beneficially owns at least 5.0% (but less than 7.5%) of our outstanding share capital, and (iii) one director nominee, so long as the other group beneficially owns at least 2.5% (but less than 5.0%) of our outstanding share capital. In addition, to the extent that after the designation of the foregoing director nominees there are additional director vacancies, each of the Recanati Group and Damar Group have agreed to vote the ordinary shares beneficially owned by them in favor of such additional director nominees designated by the party who beneficially owns the larger voting rights in our company.

FIMI Private Placements

On January 20, 2020, we entered into a share purchase agreement with the FIMI Funds to purchase, in a private placement, an aggregate of 4,166,667 ordinary shares at a price of $6.00 per share, for an aggregate $25 million gross proceeds. Concurrently, we entered into a registration rights agreement with the FIMI Funds, pursuant to which the FIMI Funds are entitled to customary demand registration rights (effective six months following the closing of the transaction) and piggyback registration rights with respect to our shares held by them. Upon the closing of the private placement, the beneficial ownership of the FIMI Funds increased from approximately 12.15% to 21.13% of our outstanding ordinary shares.

On May 23, 2023, we entered into a share purchase agreement with the FIMI Funds to purchase, in a private placement, an aggregate 12,631,579 ordinary shares at a price of $4.75 per share, for an aggregate $60 million gross proceeds. The private placement was approved by our shareholders on August 29, 2023, in accordance with Israeli law. Upon the closing of the private placement on September 7, 2023, the beneficial ownership of the FIMI Funds increased from approximately 21.08% to 38.4% of our outstanding ordinary shares and the FIMI Opportunity Funds became our controlling shareholder, within the meaning of the Companies Law. Concurrently with the execution of the share purchase agreement, we entered into an amended and restated registration rights agreement with the FIMI Funds pursuant to which, among other things, we undertook to file with the SEC a registration statement registering the resale of all of the ordinary shares held by the FIMI Funds, per its request, at any time commencing six months following the closing of the private placement.

Lilach Asher-Topilsky, the Chairman of our board of directors, Ishay Davidi and Uri Botzer, members of our board of directors, are partners of the FIMI Funds. For details regarding the beneficial ownership of the FIMI Funds and Messrs. Davidi and Botzer and Ms. Asher Topilsky see "Item 7. Major Shareholders and Related Party Transactions — Major Shareholders" and "Item 6. Directors, Senior Management and Employees — Share Ownership."

Engagements with Suppliers and Service Providers Affiliated with the FIMI Funds

We have entered into certain agreements in the ordinary course of our business for the purchase of certain products and services (such as security services, office equipment and recycling services) from entities controlled by or affiliated with the FIMI Funds, all of which were originally entered into prior to the FIMI Funds becoming a shareholder of our company and on an arm's length basis, one of which was subsequently superseded by a new agreement entered into between the parties prior to the FIMI Funds becoming our controlling shareholder. These agreements include customary terms and conditions as applicable to the type of supplied product or services.

Item 8. Financial Information

Consolidated Financial Statements

Consolidated financial statements are set forth under Item 18.

Legal Proceedings

In May 2022, we terminated a distribution agreement with a third-party engaged to distribute our proprietary products in Russia and Ukraine (the "Distributor") and a power of attorney granted in connection with such distribution agreement to an affiliate of the Distributor (the "Affiliate"). In July 2022, the Affiliate filed a request for a conciliation hearing with the court in Geneva relying on the terminated power of attorney and seeking damages for the alleged inability to sell the remaining product inventory previously acquired from the Company and compensation for the lost customer base. The conciliation hearing was held on March 17, 2023, and the Affiliate was granted authorization to proceed to file a Statement of Claim before the competent tribunal within three months. On June 13, 2023, the Affiliate filed its Statement of Claim with the tribunal of first instance in Geneva, seeking alleged damages in the total amount of $6.7 million. We were officially notified of such filing on November 17, 2023. We have filed a motion with the tribunal of first instance in Geneva challenging its jurisdiction over the Affiliate's claims, submitting that such claims should have been brought before an arbitral tribunal, as contractually agreed between the parties. Until the tribunal of first instance in Geneva rules on the motion, the Affiliate's claims will not be heard. To date, based on advice of our external legal counsel, it is not possible to assess the prospects of the claim against us and any potential liabilities and impact on our business.

In addition to the above, we are subject to various claims and legal actions during the ordinary course of our business. We believe that there are currently no claims or legal actions that would have a material adverse effect on our financial position, operations or potential performance.

Dividend Policy

We have never declared or paid any dividends on our ordinary shares. We do not anticipate paying any dividends in the foreseeable future. We currently intend to retain future earnings, if any, to finance operations and expand our business. Our board of directors has sole discretion whether to pay dividends. If our board of directors decides to pay dividends, the form, frequency and amount will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our directors may deem relevant.

Our ability to distribute dividends may be limited by future contractual obligations and by Israeli law. The Israeli Companies Law restricts our ability to declare dividends. Unless otherwise approved by a court, we can distribute dividends only from "profits" (as defined by the Israeli Companies Law), and only if there is no reasonable concern that the dividend distribution will prevent us from meeting our existing and foreseeable obligations as they become due. See Exhibit 2.1 "Description of Securities—Dividend and Liquidation Rights." The payment of dividends may be subject to Israeli withholding taxes. See *"*Item 10. Additional Information — *E. Taxation — Israeli Tax Considerations and Government Programs* — Taxation of Our Shareholders — Dividends*."*

B. Significant Changes

Except as disclosed elsewhere in this Annual Report, there have been no other significant changes since December 31, 2023, until the date of the filing of this Annual Report.

Item 9. The Offer and Listing

A. Offer and Listing Details

Our ordinary shares are quoted on the Nasdaq Global Select Market and the TASE under the symbol "KMDA."

B. Plan of Distribution

Not applicable.

C. Markets for Ordinary Shares

See "—Offer and Listing Details" above.

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. Memorandum and Articles of Association

A copy of our amended and restated articles of association is attached as Exhibit 1.1 to this Annual Report. Other than as set forth below, the information called for by this Item is set forth in Exhibit 2.1 to this Annual Report and is incorporated by reference into this Annual Report.

Establishment and Purposes of the Company

We were incorporated under the laws of the State of Israel on December 13, 1990 under the name Kamada Ltd. We are registered with the Israeli Registrar of Companies in Jerusalem. Our registration number is 51-152460-5. Our purpose as set forth in our amended articles of association is to engage in any lawful business.

Shareholder Meetings

Under the Companies Law, we are required to convene an annual general meeting of our shareholders at least once every calendar year and within a period of not more than 15 months following the preceding annual general meeting. In addition, the Companies Law provides that our board of directors may convene a special general meeting of our shareholders whenever it sees fit and is required to do so upon the written request of (i) two directors or one quarter of the serving members of our board of directors, or (ii) one or more holders of 5% or more of our outstanding share capital and 1% of our voting power, or the holder or holders of 5% or more of our voting power.

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, which, as a company listed on an exchange outside Israel, may be between four and 40 days prior to the date of the meeting. The Companies Law requires that resolutions regarding the following matters (among others) be approved by our shareholders at a general meeting: amendments to our articles of association; appointment, terms of service and termination of service of our auditors; election of external directors; approval of certain related party transactions; increases or reductions of our authorized share capital; mergers; and the exercise of our board of director's 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 essential for our proper management.

The chairman of our board of directors presides over our general meetings. However, if at any general meeting the chairman is not present within 15 minutes after the appointed time or is unwilling to act as chairman of such meeting, then the shareholders present will choose any other person present to be chairman of the 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, which, as company listed also on an exchange outside of Israel, may be between four and 40 days prior to the date of the meeting.

Israeli law requires that a notice of any annual general meeting or special general meeting be provided to shareholders at least 21 days prior to the meeting and if the agenda of the meeting includes, among other things, the appointment or removal of directors, the approval of transactions with office holders or interested or related parties, an approval of a merger or the approval of the compensation policy, notice must be provided at least 35 days prior to the meeting.

Borrowing powers

Pursuant to the Companies Law and our amended and restated articles of association, our board of directors may exercise all powers and take all actions that are not required under law or under our amended and restated articles of association to be exercised or taken by our shareholders, including the power to borrow money for company purposes.

C. Material Contracts

We have not entered into any material contracts other than in the ordinary course of business and other than those described in "Item 4. Information on the Company" or elsewhere in this Annual Report.

D. Exchange Controls

There are currently no Israeli currency control restrictions on remittances of dividends on our ordinary shares, proceeds from the sale of the ordinary shares or interest or other payments to non-residents of Israel, except for shareholders who are subjects of countries that are, or have been, in a state of war with Israel.

Non-residents of Israel who hold our ordinary shares are able to repatriate any dividends (if any), any amounts received upon the dissolution, liquidation and winding up of our affairs and proceeds of any sale of our ordinary shares, into non-Israeli currency at the rate of exchange prevailing at the time of conversion, provided that any applicable Israeli income tax has been paid or withheld on these amounts. In addition, the statutory framework for the potential imposition of exchange controls has not been eliminated, and may be restored at any time by administrative action.

E. Taxation

The following description is not intended to constitute a complete analysis of all tax consequences relating to the acquisition, ownership and disposition of our ordinary shares. You should consult your own tax advisor concerning the tax consequences of your particular situation, as well as any tax consequences that may arise under the laws of any state, local, foreign or other taxing jurisdiction.

Israeli Tax Considerations and Government Programs

The following is a brief summary of the material Israeli tax laws applicable to us, and certain Israeli Government programs benefiting us. This section also contains a discussion of material Israeli tax consequences concerning the ownership of and disposition of our ordinary shares. This summary does not discuss all aspects of Israeli tax law that may be relevant to a particular investor in light of his or her personal investment circumstances or to some types of investors, such as traders in securities, who are subject to special treatment under Israeli law. The discussion below is subject to amendment under Israeli law or changes to the applicable judicial or administrative interpretations of Israeli law, which could affect the tax consequences described below.

The discussion below does not cover all possible tax considerations. 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 our ordinary shares, including in particular, the effect of any foreign, state or local taxes.

General Corporate Tax Structure in Israel

Israeli companies are generally subject to corporate tax, which has decreased in recent years, from a rate of 25% in 2016 to 24% in 2017 and further decreased to 23% in 2018 and thereafter. However, the effective corporate tax rate payable by a company that derives income from an Approved Enterprise, a Privileged Enterprise or a Preferred Enterprise (as discussed below) may be considerably less. Capital gains generated by an Israeli company are generally subject to tax at the corporate tax rate.

Law for the Encouragement of Industry (Taxes), 1969

The Law for the Encouragement of Industry (Taxes), 1969 (the "Encouragement of Industry Law"), provides several tax benefits to "Industrial Companies." Pursuant to the Encouragement of Industry Law, a company qualifies as an Industrial Company if it is a resident of Israel and at least 90% of its income in any tax year (exclusive of income from certain defense loans) is generated from an "Industrial Enterprise" that it owns and is located in Israel or in the "Area", in accordance with its definition under section 3A of the Israeli Income Tax Ordinance. An Industrial Enterprise is defined as an enterprise whose principal activity, in a given tax year, is industrial activity.

An Industrial Company is entitled to certain tax benefits, including: (i) a deduction of the cost of purchases of patents and know-how and the right to use patents and know-how used for the development or promotion of the Industrial Enterprise in equal amounts over a period of eight years, beginning from the year in which such rights were first used, (ii) the right to elect to file consolidated tax returns, under certain conditions, with additional Israeli Industrial Companies controlled by it, and (iii) the right to deduct expenses related to public offerings in equal amounts over a period of three years beginning from the year of the offering.

Eligibility for benefits under the Encouragement of Industry Law is not contingent upon the approval of any governmental authority.

We believe that we may qualify as an Industrial Company within the meaning of the Encouragement of Industry Law; however, there is no assurance that we qualify or will continue to qualify as an Industrial Company or that the benefits described above will be available in the future.

To date, we have not utilized any tax benefits under the Encouragement of Industry Law.

Law for the Encouragement of Capital Investments, 1959

Our facilities in Israel were granted Approved Enterprise status under the Law for the Encouragement of Capital Investments, 1959, commonly referred to as the "Investment Law".

The Israeli Law for the Encouragement of Capital Investments, 1959, commonly referred to as the "Investment Law," which has undergone major reforms and several amendments in recent years, provides certain tax benefits to eligible facilities. The different benefits under the Investment Law depend on the specific year in which the enterprise received approval from the Investment Center or the year it was eligible for Approved/Privileged/Preferred Enterprise status under the Investment Law, and the benefits available at that time. Below is a short description of the different benefits available to us under the Investment Law:

Approved Enterprise

The Investment Law provides that a capital investment in eligible production facilities (or other eligible assets) may, upon application to the Investment Center, be designated as an "Approved Enterprise." Each certificate of approval for an Approved Enterprise relates to a specific investment program delineated both by its financial scope, including its sources of capital, and by its physical characteristics, for example, the equipment to be purchased and utilized pursuant to the program. The tax benefits generated from any such certificate of approval relate only to taxable income attributable to the specific Approved Enterprise.

One of our facilities was granted Approved Enterprise status by the Investment Center, which made us eligible for a grant and certain tax benefits under the "Grant Track." The approved investment program provided us with a grant in the amount of 24% of our approved investments, in addition to certain tax benefits, which applied to our turnover resulting from the operation of such investment program, for a period of up to ten consecutive years from the first year in which we generated taxable income. The tax benefits under the Grant Track include accelerated depreciation and amortization for tax purposes as well as a tax exemption for the first two years of the benefit period and the taxation of income generated from an Approved Enterprise at a reduced corporate tax rate of 10%-25% (depending on the level of foreign investment in each year), for a certain period of time. The benefit period is ordinarily seven to ten years commencing with the year in which the Approved Enterprise first generates taxable income. The benefit period is limited to 12 years from the earlier of the operational year as determined by the Investment Center or 14 years from the date of approval of the Approved Enterprise.

The Company's benefit period ended by 2017.

Privileged Enterprise

We obtained a tax ruling from the Israel Tax Authority according to which, among other things, our activity was qualified as an "industrial activity", as defined in the Investment Law and was eligible for tax benefits as a Privileged Enterprise under the "Tax Benefit Track," which apply to the turnover attributed to such enterprise, for a period of up to ten years from the first year in which we generated taxable income.

On April 1, 2005, an amendment to the Investment Law came into effect (the "2005 Amendment"), which revised the criteria for investments qualified to receive tax benefits. An eligible investment program under the 2005 Amendment will qualify for benefits as a "Privileged Enterprise" (rather than the previous terminology of Approved Enterprise). Pursuant to the 2005 Amendment, a company whose facilities meet certain criteria set forth in the 2005 Amendment may claim certain tax benefits offered by the Investment Law (as further described below) directly in its tax returns, without the need to obtain prior approval. In order to receive the tax benefits, the company must make an investment in the Privileged Enterprise which meets all of the conditions, including exceeding a certain percentage or a minimum amount, specified in the Investment Law. Such investment must be made over a period of no more than three years ending at the end of the year in which the company requested to have the tax benefits apply to the Privileged Enterprise (the "Year of Election"). According to the tax ruling mentioned above, our Year of Election is 2009. We also subsequently elected 2012 as a Year of Election. The duration of tax benefits is subject to a limitation of the earlier of seven to ten years from the first year in which the company generated taxable income (at or after the Year of Election), or 12 years from the first day of the Year of Election. Therefore, the tax benefits under our Privileged Enterprise expired at the end of 2023.

The term "Privileged Enterprise" means an industrial enterprise which is "competitive" and contributes to the gross domestic product, and for which a minimum entitling investment was made in order to establish it (as explained above). For this purpose, an industrial enterprise is deemed to be competitive and contributing to the gross domestic product if it meets one of the following conditions: (1) its main activity is in the field of biotechnology or nanotechnology, as certified by the Director of the Industrial Research and Development Administration before the project was approved; or (2) its income during a tax year from sales to a certain market does not exceed 75% of its total income from sales in that tax year; or (3) 25% or more of its total income from sales in the tax year is from sales to a certain market with at least 14,000,000 inhabitants.

A corporate taxpayer owning a Privileged Enterprise may be entitled to an exemption from corporate tax on undistributed income for a period of two to ten years, depending on the location of the Privileged Enterprise within Israel, as well as a reduced corporate tax rate of 10% to 25% for the remainder of the benefit period, depending on the level of foreign investment in each year. In addition, the Privileged Enterprise is entitled to claim accelerated depreciation for manufacturing assets used by the Privileged Enterprise.

However, a company that pays a dividend out of income generated during the tax exemption period from the Privileged/Approved Enterprise is subject to deferred corporate tax with respect to the otherwise exempt income (grossed-up to reflect the pre-tax income that we would have had to earn in order to distribute the dividend) at the corporate tax rate which would have applied if the company had not enjoyed the exemption (i.e. at a tax rate between 10% and 25%, depending on the level of foreign investment). A company is generally required to withhold tax on such distribution at a rate of 15% (or a reduced rate under an applicable double tax treaty, subject to the approval by the Israel Tax Authority).

Preferred Enterprise

An amendment to the Investment Law that became effective on January 1, 2011 ("Amendment No. 68") changed the benefit alternatives available to companies under the Investment Law and introduced new benefits for income generated by a "Preferred Company" through its "Preferred Enterprises" (as such terms are defined in the Investment Law). The definition of a Preferred Company includes a company incorporated in Israel that is not wholly owned by a governmental entity, and that, among other things, owns a Preferred Enterprise and is controlled and managed from Israel. The tax benefits granted to a Preferred Company are determined depending on the location of its Preferred Enterprise within Israel. Amendment No. 68 imposes a reduced flat corporate tax rate which is not program-dependent and applies to the Preferred Company's "preferred income" which is generated by its Preferred Enterprise.

According to the Investment Law, a Preferred Company is subject to reduced corporate tax rate of 10% for preferred income attributed to Preferred Enterprises located in areas in Israel designated as Development Zone A and 15% for those located elsewhere in Israel in the tax years 2011-2012, and 7% for Development Zone A and 12.5% for the rest of Israel in the tax year 2013, and 9% for Development Zone A and 16% for the rest of Israel in the tax years 2014 until 2016. Under an amendment to the Investment Law that became effective on January 1, 2017, the corporate tax rate applying to income attributed to Preferred Enterprise located in Development Zone A was reduced to 7.5% while the reduced corporate tax rate for the rest of Israel remains 16%. Income derived by a Preferred Company from a "Special Preferred Enterprise" (as such term is defined in the Investment Law) would be entitled, during a benefits period of 10 years, to further reduced tax rates of 5% if the Special Preferred Enterprise is located in Development Zone A, or 8% if the Special Preferred Enterprise is located elsewhere in Israel.

The tax benefits under Amendment No. 68 also include accelerated depreciation and amortization for tax purposes during the first five-year period for productive assets that the Preferred Enterprise uses pursuant to the rates prescribed in the Investment Law. Preferred Enterprises located in specific locations within Israel (Development Zone A) are eligible for grants and/or loans approved by the Israeli Investment Center, as well as tax benefits. Our facility in Beit-Kama, Israel, is located in Development Zone A.

A dividend distributed from income which is attributed to a Preferred Enterprise/Special Preferred Enterprise will generally be subject to withholding tax at source at the following rates: (i) Israeli resident corporation – 0%, (ii) Israeli resident individual – 20% (iii) non-Israeli resident – 20% subject to a reduced tax rate under the provisions of an applicable double tax treaty.

The provisions of Amendment No. 68 do not apply to existing Privileged Enterprises or Approved Enterprises, which will continue to be entitled to the tax benefits under the Investment Law as in effect prior to Amendment No. 68. Nevertheless, a company owning such enterprises may choose to apply Amendment No. 68 to its existing enterprises while waiving benefits provided under the Investment Law as in effect prior to Amendment No. 68. Once a company elects to be classified as a Preferred Enterprise under the provisions of Amendment No. 68, the election cannot be rescinded and such company will no longer enjoy the tax benefits of its Approved/Privileged Enterprises.

To date, we have not elected to be classified as a Preferred Enterprise under Amendment No. 68.

Tax benefits under the 2017 Amendment that became effective on January 1, 2017

An amendment to the Investment Law was enacted as part of the Economic Efficiency Law that was published on December 29, 2016 and became effective as of January 1, 2017 (the "2017 Amendment"). The 2017 Amendment provides new tax benefits for two types of "Technology Enterprises", as described below, and is in addition to the other existing tax beneficial programs under the Investment Law.

The 2017 Amendment provides that a technology company satisfying certain conditions will qualify as a "Preferred Technology Enterprise" and will thereby enjoy a reduced corporate tax rate of 12% on income that qualifies as "Preferred Technology Income", as defined in the Investment Law. The tax rate is further reduced to 7.5% for a Preferred Technology Enterprise located in Development Zone A. In addition, a Preferred Technology Company will enjoy a reduced corporate tax rate of 12% on capital gain derived from the sale of certain "Benefitted Intangible Assets" (as defined in the Investment Law) to a related foreign company if the Benefitted Intangible Assets were acquired from a foreign company on or after January 1, 2017 for at least NIS 200 million, and the sale receives prior approval from the National Authority for Technological Innovation ("NATI").

The 2017 Amendment further provides that a technology company satisfying certain conditions will qualify as a "Special Preferred Technology Enterprise" and will thereby enjoy a reduced corporate tax rate of 6% on "Preferred Technology Income" regardless of the company's geographic location within Israel. In addition, a Special Preferred Technology Enterprise will enjoy a reduced corporate tax rate of 6% on capital gain derived from the sale of certain "Benefitted Intangible Assets" to a related foreign company if the Benefitted Intangible Assets were either developed by the Special Preferred Technology Enterprise or acquired from a foreign company on or after January 1, 2017, and the sale received prior approval from NATI. A Special Preferred Technology Enterprise that acquires Benefitted Intangible Assets from a foreign company for more than NIS 500 million will be eligible for these benefits for at least ten years, subject to certain approvals as specified in the Investment Law.

Dividends distributed by a Preferred Technology Enterprise or a Special Preferred Technology Enterprise, paid out of Preferred Technology Income, are generally subject to withholding tax at source at the rate of 20% or such lower rate as may be provided in an applicable tax treaty (subject to the receipt in advance of a valid certificate from the Israel Tax Authority allowing for a reduced tax rate). However, if such dividends are paid to an Israeli company, generally no tax is required to be withheld. If such dividends are distributed to a foreign company and other conditions are met, the withholding tax rate will generally be 4%.

We have applied for a new tax ruling from the Israel Tax Authority according to which, if approved, among other things, our activity would be qualified as an "industrial activity," as defined in Investment Law, and we may be eligible for tax benefits according to the Investment Law, and our income from sales of our proprietary products (including royalties-based income) would be deemed "Preferred Technology Income" and "Preferred income" (within the meaning of the Investment Law).

There can be no assurance that we will comply with the conditions required to remain eligible for benefits under the Investment Law in the future, including under the tax ruling (if obtained), or that we will be entitled to any additional benefits thereunder. If we do not fulfill these conditions in whole or in part, the benefits can be canceled and we may be required to refund the amount of the benefits, linked to the Israeli consumer price index, with interest.

Tax benefits under the 2021 Amendment that became effective on August 15, 2021

Israel's 2021-2022 Budget Law published on November 15, 2021 (the "2021 Amendment"), introduced a new dividend distribution ordering rule according to which in the event of a dividend distribution, earnings that were tax exempt under the historical Approved or Beneficial Enterprise regimes, and that were accrued or derived until December 31, 2020, referred to as "trapped earnings," must be distributed on a pro-rata basis from any dividend distribution, commencing August 15, 2021 and onwards.

To date, we have not utilized any tax benefits under the Investment Law and therefore, we do not have "trapped earnings."

The Encouragement of Industrial Research, Development and Technological Innovation in the Industry Law, 5744-1984 (formerly known as The Encouragement of Industrial Research and Development Law, 5744-1984)

We have received grants from the Government of the State of Israel through the Israel Innovation Authority of the Israeli Ministry of Economy and Industry (the "IIA") (formerly known as the Office of the Chief Scientist of the Israeli Ministry of Economy (the "OCS")), for the financing of a portion of our research and development expenditures pursuant to the Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984 (formerly known as the Encouragement of Industrial and Development Law, 5744-1984) (the "Research Law") and related regulations. We previously received funding from the IIA for eight research and development programs, in the aggregate amount of approximately $2.0 million as of December 31, 2023, which amount has accrued aggregate interest of approximately $43,623 as of such date, and we had paid aggregate royalties to the IIA for these programs in the amount of approximately $1.1 million and had a contingent liability to the IIA in the amount of approximately $0.9 million (excluding any interest thereon) as of December 31, 2023.

Under the Research Law, research and development programs which meet specified criteria and are approved by the IIA (formerly the OCS) are eligible for grants. Under the Research Law, as currently in effect, the grants awarded are typically up to 50% of the project's expenditures. The grantee is required to pay royalties to the State of Israel from the sale of products developed under the program. Regulations under the Research Law, as currently in effect, generally provide for the payment of royalties of 3% to 5% on sales of products and services based on technology developed using grants, until 100% (which may be increased under certain circumstances) of the U.S. dollar-linked value of the grant is repaid, with interest at the rate of 12-month LIBOR. The terms of the IIA grants generally require that products developed with such grants be manufactured in Israel and that the technology developed thereunder may not be transferred outside of Israel, unless approval is received from the IIA and additional payments are made to the State of Israel. However, this does not restrict the export of products that incorporate the funded technology. The royalty repayment ceiling can reach up to three times the amount of the grant received if manufacturing is moved outside of Israel, and if the funded technology itself is transferred outside of Israel, the royalty ceiling can reach up to six times the amount of grants (plus interest). Even following the full repayment of any IIA grants, we must nevertheless continue to comply with the requirements of the Research Law. If we fail to comply with any of the conditions and restrictions imposed by the Research Law, or by the specific terms under which we received the grants, we may be required to refund any grants previously received together with interest and penalties, and, in certain circumstances, may be subject to criminal charges.

Taxation of Our Shareholders

The Israeli Income Tax Ordinance applies Israeli income tax on a worldwide basis with respect to Israeli residents, and on an Israeli source income, with respect to non-Israeli residents. Dividends distributed (or deemed distributed) by an Israeli resident company to a holder in respect of its securities and consideration received by a holder (or deemed received) in connection with the sale or other disposition of securities of an Israeli resident company are considered to be an Israeli source income.

Capital Gains

Under present Israeli tax legislation, the tax rate applicable to real capital gain derived by Israeli resident corporations from the sale of shares of an Israeli company is the general corporate tax rate (currently, 23%).

Generally, as of January 1, 2006, the tax rate applicable to real capital gain derived by Israeli individuals from the sale of shares which had been purchased on or after January 1, 2003, whether or not listed on a stock exchange, is 25%, unless such shareholder claims a deduction for interest and linkage differences expenses in connection with the purchase and holding of such shares. Additionally, if such a shareholder is considered a "Substantial Shareholder" (*i.e.,* a person who holds, directly or indirectly, alone or together with another, 10% or more of any of the company's "means of control" (including, among other things, the right to receive profits of the company, voting rights, the right to receive the company's liquidation proceeds and the right to appoint a director)) 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%. Individual shareholders dealing in securities in Israel are taxed at their marginal tax rates applicable to business income (up to 47% from 2017).

Notwithstanding the foregoing, capital gains generated from the sale of shares by a non-Israeli shareholder may be exempt from Israeli taxes provided that, in general, both the following conditions are met: (i) the seller of the shares does not have a permanent establishment in Israel to which the generated capital gain is attributed and (ii) if the seller is a corporation, less than 25% of its means of control are held, directly and indirectly, by Israeli residents or Israeli residents that are the beneficiaries or are eligible to less than 25% of the seller's income or profits from the sale. In addition, the sale of the shares may be exempt from Israeli capital gain tax under the provisions of an applicable tax treaty. For example, the Convention between the Government of the United States of America and the Government of Israel with respect to Taxes on Income, or the "Israel-U.S.A. Double Tax Treaty," generally exempts U.S. residents from Israeli capital gains tax in connection with such sale, provided that (i) the U.S. resident owned, directly or indirectly, less than 10% of the Israeli resident company's voting power at any time within the 12-month period preceding such sale; (ii) the seller, if an individual, has been present in Israel for less than 183 days (in the aggregate) during the taxable year; and (iii) the capital gain from the sale was not generated through a permanent establishment of the U.S. resident in Israel.

The purchaser of the shares, the stockbrokers who effected the transaction or the financial institution holding the shares through which payment to the seller is made are obligated, subject to the above-referenced exemptions if certain conditions are met, to withhold tax on the real capital gain resulting from a sale of shares at the rate of 25%.

A detailed return, including a computation of the tax due, must be filed and an advance payment must be paid on January 31 and July 31 of each tax year for sales of shares traded on a stock exchange made within the six months preceding the month of the report. However, if the seller is exempt from tax or all tax due was withheld at the source according to applicable provisions of the Israeli Income Tax Ordinance and the regulations promulgated thereunder, the return does not need to be filed and an advance payment does not need to be made. Taxable capital gains are also reportable on an annual income tax return if applicable.

Dividends

Our company is obligated to withhold tax, at the rate of 15%, upon the distribution of a dividend attributed to a Privileged Enterprise's income, subject to a reduced tax rate under the provisions of an applicable double tax treaty, provided that a certificate from the Israel Tax Authority allowing for a reduced withholding tax rate is obtained in advance. If the dividend is distributed from income not attributed to a Privileged Enterprise, the following withholding tax rates will generally apply: (i) Israeli resident corporations — 0%, (ii) Israeli resident individuals — 25% (or 30% in the case of a Substantial Shareholder) and (iii) non-Israeli residents (whether an individual or a corporation), so long as the shares are registered with a nominee company — 25%, subject to a reduced tax rate under the provisions of an applicable double tax treaty, provided that a certificate from the Israel Tax Authority allowing for a reduced withholding tax rate is obtained in advance. Generally, unless the recipient of the dividend is a U.S. corporate resident which holds at least 10% of the share capital of the Company, the withholding rate will not be reduced under the Israel-U.S.A. Double Tax Treaty.

Excess Tax

An additional tax liability at the rate of 3% in 2017 onwards is added to the applicable tax rate on the annual taxable income of individuals (whether any such individual is an Israeli resident or non-Israeli resident) exceeding NIS 663,240 in 2022, NIS 698,280 in 2023 and NIS 721,560 in 2024.

Estate and gift tax

Israeli law presently does not impose estate or gift taxes.

United States Federal Income Taxation

The following is a description of the material U.S. federal income tax consequences to a U.S. Holder (as defined below) of the acquisition, ownership and disposition of our ordinary shares. This description addresses only the U.S. federal income tax consequences to holders of our ordinary shares in the United States that will hold our ordinary shares as capital assets for U.S. federal income tax purposes. This description does not address many of the tax considerations applicable to holders that may be subject to special tax rules, including, without limitation:

- banks, certain financial institutions or insurance companies;
- real estate investment trusts, regulated investment companies or grantor trusts;
- dealers or traders in securities, commodities or currencies;
- tax-exempt entities;
- certain former citizens or long-term residents of the United States;
- persons that received our shares as compensation for the performance of services;
- persons that will hold our shares as part of a "hedging," "integrated" or "conversion" transaction or as a position in a "straddle" for U.S. federal income tax purposes;
- partnerships (including entities classified as partnerships for U.S. federal income tax purposes) or other pass-through entities, or holders that will hold our shares through such an entity;
- S-corporations;
- persons whose "functional currency" is not the U.S. Dollar;
- persons that own directly, indirectly or through attribution 10% or more of the voting power or value of our shares; or
- persons holding our ordinary shares in connection with a trade or business conducted outside the United States.

Moreover, this description does not address the U.S. federal estate, gift or alternative minimum tax consequences, or any state, local or foreign tax consequences, of the acquisition, ownership and disposition of our ordinary shares.

This description is based on the U.S. Internal Revenue Code of 1986, as amended, (the "Code"), existing, proposed and temporary U.S. Treasury Regulations and judicial and administrative interpretations thereof, in each case as in effect on the date hereof. All of the foregoing is subject to change, which change could apply retroactively and could affect the tax consequences described below. There can be no assurance that the U.S. Internal Revenue Service ("IRS") will not take a different position concerning the tax consequences of the acquisition, ownership and disposition of our ordinary shares or that the IRS's position would not be sustained.

For purposes of this description, a "U.S. Holder" is a beneficial owner of our ordinary shares that, for U.S. federal income tax purposes, is:

- a citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States or any jurisdiction thereof; or
- a trust or estate the income of which is subject to United States federal income taxation regardless of its source.

Holders should consult their tax advisors with respect to the U.S. federal, state, local and foreign tax consequences of acquiring, owning and disposing of our ordinary shares.

Distributions

Subject to the discussion below under "Passive Foreign Investment Company Considerations," the gross amount of any distribution made to a U.S. Holder with respect to our ordinary shares before reduction for any Israeli taxes withheld therefrom, other than certain pro rata distributions of our ordinary shares to all our shareholders, generally will be includible in the U.S. Holder's income as dividend income to the extent the distribution is paid out of our current or accumulated earnings and profits as determined under U.S. federal income tax principles. Subject to the discussion below under "Passive Foreign Investment Company Considerations," non-corporate U.S. Holders may qualify for the lower rates of taxation with respect to dividends on ordinary shares applicable to long-term capital gains (i.e., gains from the sale of capital assets held for more than one year) provided that certain conditions are met, including certain holding period requirements and the absence of certain risk reduction transactions. However, dividends on our ordinary shares will not be eligible for the dividends received deduction generally allowed to corporate U.S. Holders. Subject to the discussion below under "Passive Foreign Investment Company Considerations," to the extent that the amount of any distribution by us exceeds our current and accumulated earnings and profits as determined under U.S. federal income tax principles, it will be treated first as a tax-free return of tax basis in our ordinary shares and thereafter as capital gain. We do not expect to maintain calculations of our earnings and profits under U.S. federal income tax principles and, therefore, U.S. Holders should expect that the entire amount of any distribution generally will be reported as dividend income.

Dividends paid to U.S. Holders with respect to our ordinary shares will be treated as foreign source income, which may be relevant in calculating a U.S. Holder's foreign tax credit limitation. Subject to certain conditions and limitations, Israeli tax withheld on dividends may be deducted from taxable income or credited against U.S. federal income tax liability. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends that we distribute generally should constitute "passive category income," or, in the case of certain U.S. Holders, "general category income." A foreign tax credit for foreign taxes imposed on distributions may be denied if certain minimum holding period requirements are not satisfied. The rules relating to the determination of the foreign tax credit are complex, and U.S. Holders should consult their tax advisors to determine whether and to what extent they will be entitled to this credit.

Sale, Exchange or Other Disposition of Ordinary Shares

Subject to the discussion below under "Passive Foreign Investment Company Considerations," U.S. Holders generally will recognize gain or loss on the sale, exchange or other disposition of our ordinary shares equal to the difference between the amount realized on the sale, exchange or other disposition and the holder's tax basis in our ordinary shares, and any gain or loss will be capital gain or loss. The tax basis in an ordinary share generally will be equal to the cost of the ordinary share. For non-corporate U.S. Holders, capital gain from the sale, exchange or other disposition of ordinary shares is generally eligible for a preferential rate of taxation in the case of long-term capital gain. The deductibility of capital losses for U.S. federal income tax purposes is subject to limitations under the Code. Any gain or loss that a U.S. Holder recognizes generally will be treated as U.S. source income or loss for foreign tax credit limitation purposes.

Passive Foreign Investment Company Considerations

If we were to be classified as a "passive foreign investment company" ("PFIC") in any taxable year, a U.S. Holder would be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. Holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

A non-U.S. corporation will be classified as a PFIC for U.S. federal income tax purposes in any taxable year in which, after applying certain look-through rules, either

- at least 75% of its gross income is "passive income", or
- at least 50% of the average quarterly value of its gross assets is attributable to assets that produce passive income or are held for the production of passive income.

Passive income for this purpose generally includes dividends, interest, royalties, rents, gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income and amounts derived by reason of the temporary investment of funds raised in offerings of our ordinary shares. If a non-U.S. corporation owns at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as directly receiving its proportionate share of the other corporation's income. If we are classified as a PFIC in any year with respect to which a U.S. Holder owns our ordinary shares, we generally will continue to be treated as a PFIC with respect to that U.S. Holder in all succeeding years during which the U.S. Holder owns our ordinary shares, regardless of whether we continue to meet the tests described above.

However, our PFIC status for each taxable year may be determined only after the end of such year and will depend on the composition of our income and assets, our activities and the value of our assets (which may be determined in large part by reference to the market value of our ordinary shares, which may be volatile) from time to time. If we are a PFIC then unless a U.S. Holder makes one of the elections described below, a special tax regime will apply to both (i) any "excess distribution" by us to that U.S. Holder (generally, the U.S. Holder's ratable portion of distributions in any year which are greater than 125% of the average annual distribution received by the holder in the shorter of the three preceding years or its holding period for our ordinary shares) and (ii) any gain realized on the sale or other disposition of the ordinary shares.

Under this regime, any excess distribution and realized gain will be treated as ordinary income and will be subject to tax as if (i) the excess distribution or gain had been realized ratably over the U.S. Holder's holding period, (ii) the amount deemed realized in each year had been subject to tax in each year of that holding period at the highest marginal rate for that year (other than income allocated to the current period or any taxable period before we became a PFIC, which will be subject to tax at the U.S. Holder's regular ordinary income rate for the current year and will not be subject to the interest charge discussed below), and (iii) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those years. In addition, dividend distributions made to a U.S. Holder will not qualify for the lower rates of taxation applicable to long-term capital gains discussed above under "Distributions." Certain elections may be available that would result in an alternative treatment (such as mark-to-market treatment) of our ordinary shares. We do not intend to provide the information necessary for U.S. Holders to make qualified electing fund elections if we are classified as a PFIC. U.S. Holders should consult their tax advisors to determine whether any of these elections would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances.

If we are determined to be a PFIC, the general tax treatment for U.S. Holders described in this paragraph would apply to indirect distributions and gains deemed to be realized by U.S. Holders in respect of any of our subsidiaries that also may be determined to be PFICs.

In addition, all U.S. Holders may be required to file tax returns (including on IRS Form 8621) containing such information as the U.S. Treasury may require. For example, if a U.S. Holder owns ordinary shares during any year in which we are classified as a PFIC and the U.S. Holder recognizes gain on a disposition of our ordinary shares or receives distributions with respect to our ordinary shares, the U.S. Holder generally will be required to file an IRS Form 8621 with respect to the company, generally with the U.S. Holder's federal income tax return for that year. The failure to file this form when required could result in substantial penalties.

Based on the financial information currently available to us and the nature of our business, we do not expect that we will be classified as a PFIC for the taxable year ended December 31, 2023. However, this determination could be subject to change. If, contrary to our expectations, we were to be classified as a PFIC, U.S. Holders of ordinary shares may be required to file form 8621 with respect to their ownership of our ordinary shares in the year in which we were a PFIC. U.S. Holders of our ordinary shares should consult their tax advisors in this regard.

Backup Withholding and Information Reporting Requirements

U.S. backup withholding and information reporting requirements may apply to payments to holders of our ordinary shares. Information reporting generally will apply to payments of dividends on, and to proceeds from the sale of, our ordinary shares made within the United States, or by a U.S. payor or U.S. middleman, to a holder of our ordinary shares, other than an exempt recipient (including a corporation). A payor may be required to backup withhold from payments of dividends on, or the proceeds from the sale or redemption of, ordinary shares within the United States, or by a U.S. payor or U.S. middleman, to a holder, other than an exempt recipient, if the holder fails to furnish its correct taxpayer identification number or otherwise fails to comply with, or establish an exemption from, the backup withholding tax requirements. Any amounts withheld under the backup withholding rules generally should be allowed as a credit against the beneficial owner's U.S. federal income tax liability, if any, and any excess amounts withheld under the backup withholding rules may be refunded, provided that the required information is timely furnished to the IRS.

Additional Medicare Tax

Certain U.S. Holders who are individuals, estates or trusts may be required to pay an additional 3.8% Medicare tax on, among other things, dividends and capital gains from the sale or other disposition of shares of common stock. For individuals, the additional Medicare tax applies to the lesser of (i) "net investment income" or (ii) the excess of "modified adjusted gross income" over $200,000 ($250,000 if married and filing jointly or $125,000 if married and filing separately). "Net investment income" generally equals the taxpayer's gross investment income reduced by the deductions that are allocable to such income. U.S. Holders will likely not be able to credit foreign taxes against the 3.8% Medicare tax.

Foreign Asset Reporting

Certain U.S. Holders who are individuals (and certain domestic entities) may be required to report information relating to an interest in our ordinary shares, subject to certain exceptions (including an exception for shares held in accounts maintained by U.S. financial institutions). 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 our ordinary shares.

The above description is not intended to constitute a complete analysis of all tax consequences relating to acquisition, ownership and disposition of our ordinary shares. Holders should consult their tax advisors concerning the tax consequences of their particular situations.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to certain of the reporting requirements of Exchange Act, as applicable to "foreign private issuers" as defined in Rule 3b-4 under the Exchange Act. Accordingly, we are required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements and other information regarding registrants like us that file electronically with the SEC. You can also inspect the Annual Report on that website. Our SEC filings are also generally available to the public via the Israel Securities Authority's Magna website at www.magna.isa.gov.il, and the TASE website at http://www.maya.tase.co.il.

A copy of each document (or a translation thereof to the extent not in English) concerning our company that is referred to in this Annual Report is available for public view (subject to confidential treatment of certain agreements pursuant to applicable law) at our principal executive offices.

I. Subsidiary Information

Not applicable.

Item 11. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We are exposed to changes in interest as our financial debt bears floating and fixed interest rates. In addition, our exposure is also related to cash balance invested in interest-bearing deposits.

Foreign Currency Risk

Fluctuations in exchange rates, especially the NIS against the U.S. dollar, may affect our results, as part of our assets is linked to NIS, as are part of our liabilities. Changes in exchange rates may also affect the prices of products purchased by us and designated for marketing in Israel in cases where these product prices are not linked to the U.S. dollar and during the period after these products are sold to our customers in NIS. In addition, the fluctuation in the NIS exchange rate against the U.S. dollar may impact our results, as a portion of our manufacturing cost is NIS denominated.

For the years ended December 31, 2023, 2022 and 2021, we have witnessed high volatility in the U.S. dollar exchange rate. This fact impacts our revenues from the Distribution segment, where prices are denominated in or linked to the NIS upon delivery of product while our expenses for the purchase of raw materials and imported goods in the Distribution segment are in U.S. dollars and part of our development and marketing expenses are paid in NIS.

We attempt to mitigate our currency exposure by matching assets denominated in NIS currency with liabilities denominated in NIS. In the Distribution segment, we attempt to mitigate foreign currency exposure by matching Euro denominated expenses with Euro denominated revenues. Additionally, we use, and from time to time, will continue to use, currency hedging transactions using financial derivatives and forward currency contracts. We attempt to enter into forward currency contracts with critical terms that match those of the underlying exposure. As of December 31, 2023, we had open transactions in derivatives in the amount of approximately $39.2 million. We regularly monitor and review the need for currency hedging transactions in accordance with trend analysis.

The following table presents information about the changes in the exchange rates of the NIS against the U.S. dollar:

Period	Change in Average Exchange Rate of the NIS against the U.S. Dollar (%)
Year ended December 31, 2020	(7.0)
Year ended December 31, 2021	(3.3)
Year ended December 31, 2022	13.2
Year ended December 31, 2023	3.1

As of December 31, 2023, we had excess liabilities over assets denominated in NIS in the amount of $9.1 million. When the U.S. dollar appreciates against the NIS, we recognize financial expenses with respect to exchange rate differences. When the U.S. dollar depreciates against the NIS, we recognize financial income.

As of December 31, 2023, we had foreign currency exposures to currencies other than U.S. dollars (mainly in EUR) amounting to $3.9 million in excess liabilities over assets. Most of this exposure is to the Euro.

A 10% increase (decrease) in the value of the NIS against the U.S. dollar would have decreased (increased) our financial assets by $0.91 million, $0.12 million and $0.06 million as of December 31, 2023, 2022 and 2021, respectively.

Item 12. Description of Securities Other Than Equity Securities

Not applicable.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

Not applicable.

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

Not applicable.

Item 15. Controls and Procedures

(a) *Disclosure Controls and Procedures*. Our management, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023, pursuant to Rule 13a-15 under the Exchange Act. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer (the principal executive and principal financial officer, respectively) have concluded that our disclosure controls and procedure are effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure, and is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms.

(b) *Report* of *Management on Internal Control over Financial Reporting*. Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our management has assessed the effectiveness of internal control over financial reporting based on the Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, our management has concluded that our internal control over financial reporting as of December 31, 2023 was effective.

(c) *Attestation Report of the Registered Public Accounting Firm*. Our independent registered public accounting firm, Kost Forer Gabbay& Kasierer, a member of Ernst & Young Global, has audited the consolidated financial statements included in this annual report on Form 20-F, and as part of its audit, has issued its audit report on the effectiveness of our internal control over financial reporting as of December 31, 2023. The report of Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, is included with our consolidated financial statements included elsewhere in this annual report and is incorporated herein by reference.

(d) *Changes in Internal Control over Financial Reporting*. During the period covered by this report, we have not made any changes to our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16. [Reserved]

Item 16A. Audit Committee Financial Expert

Our board of directors has determined that each of Assaf Itshayek and Lilach Payorski is an "independent" director for purposes of serving on an audit committee under the Exchange Act and Nasdaq listing requirements and qualifies as an "audit committee financial expert," as defined in Item 407 (d)(5) of Regulation S-K.

Item 16B. Code of Ethics

We have adopted a Code of Ethics, which applies to our directors, officers and employees, including our Chief Executive Officer and Chief Financial Officer, principal accounting officer or controller, and persons performing similar functions. The Code of Ethics is posted on our website, www.kamada.com.

Item 16C. Principal Accountant Fees and Services

During the years ended December 31, 2023 and 2022, we were billed the following aggregate fees for the professional services rendered by Kost Forer Gabbay& Kasierer, a member of Ernst & Young Global, independent registered public accounting firm, all of which were pre-approved by our Audit Committee:

	Year Ended December 31,	
	2023	2022
Audit Fees (1)	$ 430,000	365,000
Tax Fees (2)	111,243	186,445
All Other Fees (3)	8,041	-
Total	$ 549,284	551,445

(1) Audit fees are aggregate fees for audit services for each of the years shown in this table, including fees associated with the annual audit and reviews of our quarterly financial results submitted on Form 6-K, the auditor attestation report on the effectiveness of our internal control over financial reporting, consultations on various accounting issues and audit services provided in connection with other statutory or regulatory filings.
(2) Tax services rendered by our auditors in 2023 and 2022 were for compliance with tax regulation.
(3) Other fees in 2023 are for ESG related services.

Our audit committee has adopted a policy for pre-approval of audit and non-audit services provided by our independent auditor. Under the policy, such services require the specific pre-approval of our audit committee followed by ratification of our full board of directors. Any proposed services exceeding the pre-approval amounts for all services to be provided by our independent auditor require an additional specific pre-approval by our audit committee followed by the approval of our full board of directors.

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

Not applicable.

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

In the year ended December 31, 2023, neither we nor any affiliated purchaser (as defined in the Exchange Act) purchased any of our ordinary shares.

Item 16F. Change in Registrant's Certifying Accountant

None.

Item 16G. Corporate Governance

As a foreign private issuer whose shares are listed on the Nasdaq Global Select Market, we have the option to follow Israeli corporate governance practices rather than certain of those of Nasdaq, except to the extent that such laws would be contrary to U.S. securities laws and provided that we disclose the practices we are not following and describe the home country practices we follow instead. We rely on this "foreign private issuer exemption" with respect to the following Nasdaq requirements:

- *Distribution of annual and quarterly reports to shareholders*. Under Israeli law, as a public company whose shares are traded on the TASE, we are not required to distribute annual and quarterly 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 publicly available through the website of the Israel Securities Authority and the TASE. In addition, we make our audited financial statements available to our shareholders at our offices.

- *Shareholder approval requirements for equity issuances and equity-based compensation plans.* Under the Companies Law, the adoption of, and material changes to, equity-based compensation plans generally require the approval of the board of directors (for approval of equity-based arrangements, see "Item 6. Directors, Senior Management and Employees — Fiduciary Duties and Approval of Specified Related Party Transactions under Israeli Law — Disclosure of Personal Interests of a Controlling Shareholder and Approval of Certain Transactions," "Item 6. Directors, Senior Management and Employees — Compensation of Directors" and "Item 6. Directors, Senior Management and Employees — Compensation of Executive Officers"). Similarly, the approval of the board of directors is generally sufficient for a private placement unless the private placement is deemed a "significant private placement" (see "Item 6. Directors, Senior Management and Employees — Approval of Significant Private Placements"), in which case shareholder approval is also required, or an office holder or a controlling shareholder or their relative has a personal interest in the private placement, in which case, audit committee approval is required prior to the board approval and, for a private placement in which a controlling shareholder or its relative has a personal interest, shareholder approval is also required (see "Item 6. Directors, Senior Management and Employees — Fiduciary Duties and Approval of Specified Related Party Transactions under Israeli Law").

- *Requirement for independent oversight on our director nominations process and to adopt a formal written charter or board resolution addressing the nominations process.* In accordance with Israeli law and practice, directors are recommended by our board of directors for election by our shareholders. The Damar Group and Recananti Group have entered into a shareholders' agreement which includes an agreement about voting in the election of nominees appointed by the other party (see "Item 7. Major Shareholders and Related Party Transactions — Related Party Transactions — Shareholders' Agreement"). As permitted under the Companies Law, we do not have a formal charter addressing the nominations process.

- *Quorum requirement.* Under our articles of association and as permitted under the Companies Law, a quorum for any meeting of shareholders shall be the presence of at least two shareholders present in person, by proxy or by a voting instrument, who hold at least 25% of the voting power of our shares instead of 33 1/3% of the issued share capital required under Nasdaq requirements. At an adjourned meeting, any number of shareholders shall constitute a quorum.

- *Compensation Committee Charter*. As permitted under the Companies Law, we do not have a formal charter for our compensation committee.

Except as stated above, we comply with the rules generally applicable to U.S. domestic companies listed on Nasdaq. We may in the future decide to use other foreign private issuer exemptions with respect to some or all of the other Nasdaq listing requirements. Following our home country governance practices, as opposed to the requirements that would otherwise apply to a company listed on Nasdaq, may provide less protection than is accorded to investors under Nasdaq listing requirements applicable to domestic issuers. For more information, see "Item 3. Key Information —D. Risk Factors — *As we are a "foreign private issuer" and follow certain home country corporate governance practices instead of otherwise applicable Nasdaq corporate governance requirements, our shareholders may not have the same protections afforded to shareholders of domestic U.S. issuers that are subject to all Nasdaq corporate governance requirements*." We are also required to comply with Israeli corporate governance requirements under the Companies Law applicable to Israeli public companies, such as us, whose shares are listed for trade on an exchange outside Israel and dual listed on the TASE.

Item 16H. Mine Safety Disclosure

Not applicable.

Item 16I. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

Not applicable.

Item 16J. Insider trading policies

Not applicable.

Item 16K. Cybersecurity

Cybersecurity represents an important component of the Company's overall approach to risk management. The Company's cybersecurity policies, standards and practices are integrated into the Company's enterprise risk management ("ERM") approach, and cybersecurity risks are one of the enterprise risks that are subject to oversight by the Company's Board of Directors. The Company approaches cybersecurity threats through a cross-functional approach which endeavors to: (i) identify, prevent and mitigate cybersecurity threats to the Company; (ii) preserve the confidentiality, security and availability of the information that we collect and store to use in our business; (iii) protect the Company's intellectual property; (iv) maintain the confidence of our customers, clients and business partners; and (v) provide appropriate public disclosure of cybersecurity risks and incidents when required.

Risk Management and Strategy

The Company's cybersecurity program focuses on the following areas:

- **Vigilance:** The Company maintains cybersecurity threat operations with the goal of identifying, preventing and mitigating cybersecurity threats and responding to cybersecurity incidents in accordance with our established incident response and recovery plans.

- **Systems Safeguards:** The Company deploys systems safeguards that are designed to protect the Company's information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality and access controls, which are evaluated and improved through ongoing vulnerability assessments and cybersecurity threat intelligence.

- **Collaboration:** The Company utilizes collaboration mechanisms established with certain intelligence and enforcement agencies and third-party service providers, to identify, assess and respond to cybersecurity risks.

- **Third-Party Risk Management:** The Company endeavors to identify and oversee cybersecurity risks presented by third parties, as well as the systems of third parties that could adversely impact our business in the event of a cybersecurity incident affecting those third-party systems.

- **Training:** The Company provides periodic training for personnel regarding cybersecurity threats, which reinforces the Company's information security policies, standards and practices.

- **Incident Response and Recovery Planning:** The Company has established and maintains incident response and recovery plans that address the Company's response to a cybersecurity incident and the recovery from a cybersecurity incident, and such plans are tested and evaluated periodically.

- **Communication, Coordination and Disclosure:** The Company utilizes a cross-functional approach to address the risk from cybersecurity threats, involving management personnel from the Company's technology, operations, legal, risk management, and other key business functions, while also implementing controls and procedures for the escalation of cybersecurity incidents pursuant to established thresholds so that decisions regarding the disclosure and reporting of such incidents can be made by management in a timely manner.

A key part of the Company's strategy for managing risks from cybersecurity threats is the ongoing assessment and testing of the Company's processes and practices focused on evaluating the effectiveness of our cybersecurity measures. The Company engages third parties as appropriate to perform assessments of its cybersecurity measures. The results of such assessments and reviews are reported to the Company's Board of Directors and the Company adjusts its cybersecurity policies, standards, processes and practices as necessary based on the information provided by the assessments, audits and reviews.

Governance

The Company's Board of Directors receives presentations on cybersecurity risks at least once a year, which address a wide range of topics including, for example, recent developments, third-party reviews, the threat environment, technological trends and information security considerations arising with respect to the Company. The Board of Directors will receive prompt and timely information regarding any significant cybersecurity incident, as well as ongoing updates regarding such incident until it has been addressed. At least once a year, the Board discuss the Company's approach to cybersecurity risk management with the Company's management and IT Director.

The Company's IT Director is principally responsible for overseeing the Company's cybersecurity risk management program, in partnership with other business leaders across the Company. The IT Director works in coordination with the other members of management, including our Chief Executive Officer, Chief Financial Officer, and General Counsel. The Company's IT Director has served in various roles in information technology and information security for over 20 years, including at Rafael Advanced Defense Systems, Haifa Sea Port, Tara Dairy and HCT. The Company's IT Director has a bachelor's degree in information systems management and business administration and is a Microsoft systems certified engineer.

The Company's IT Director, in coordination with senior leadership, works collaboratively across the Company to implement a program designed to protect the Company's information systems from cybersecurity threats and to promptly respond to any cybersecurity incidents. To facilitate the success of this program, multidisciplinary teams throughout the Company are deployed to address cybersecurity threats and to respond to cybersecurity incidents in accordance with the Company's incident response and recovery plans. Through the ongoing communications from these teams, the IT Director and senior leadership monitor the prevention, detection, mitigation and remediation of cybersecurity incidents in real time, and report such incidents to the Board when appropriate.

To date, no risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, which have not been material, have materially affected or are reasonably likely to materially affect our business strategy, results of operations or financial condition. However, an actual or perceived breach of our cybersecurity could damage our reputation, subject us to third-party lawsuits, regulatory fines or other actions or liabilities, any of which could adversely affect our business, operating results or financial condition. For further information, see "Item 3. Key Information – D. Risk Factors – Risks Related to Our Industry – *Our business and operations would suffer in the event of computer system failures, cyber-attacks on our systems or deficiency in our cyber security measures.*"

PART III

Item 17. Financial Statements

Consolidated Financial Statements are set forth under Item 18.

Item 18. Financial Statements

Our Consolidated Financial Statements beginning on pages F-1 through F-72, as set forth in the following index, are hereby incorporated herein by reference. These Consolidated Financial Statements are filed as part of this Annual Report.

Item 19. Exhibits

Exhibit No.	Description
1.1	Amended Articles of Association of the Registrant (incorporated by reference to Appendix A2 to the Proxy Statement for the 2016 Annual General Meeting of Shareholders, filed as Exhibit 99.1 to Form 6-K filed with the Securities and Exchange Commission on July 26, 2016).
1.2	Memorandum of Association of the Registrant, as currently in effect (as translated from Hebrew) (incorporated by reference to Exhibit 3.1 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
2.1	Description of Securities (incorporated by reference to Exhibit 2.1 of the Annual Report on Form 20-F/A filed with the Securities and Exchange Commission on March 16, 2020)
2.2	Form of Certificate for Ordinary Shares (incorporated by reference to Exhibit 4.1 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.1†	Exclusive Manufacturing, Supply and Distribution Agreement, dated as of August 23, 2010, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.1 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.2†	Technology License Agreement, dated as of August 23, 2010, by and between Kamada Ltd. and Baxter Healthcare S.A. (incorporated by reference to Exhibit 10.2 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.3†	Amended and Restated Fraction IV-1 Paste Supply Agreement, dated as of August 23, 2010, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.3 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.4†	First Amendment to the Amended and Restated Fraction IV-1 Paste Supply Agreement, dated as of May 10, 2011, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.4 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.5†	Second Amendment to the Amended and Restated Fraction IV-1 Paste Supply Agreement, dated as of June 22, 2011, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.5 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.6†	License Agreement, dated as of November 16, 2006, by and between PARI GmbH and Kamada Ltd. (incorporated by reference to Exhibit 10.7 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.7†	Amendment No. 1 to License Agreement, dated as of August 9, 2007, by and between PARI GmbH and Kamada Ltd. (incorporated by reference to Exhibit 10.8 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.8†	Addendum No. 1 to License Agreement, dated as of February 21, 2008, by and between PARI Pharma GmbH and Kamada Ltd. (incorporated by reference to Exhibit 10.9 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.9†	Supply and Distribution Agreement, dated as of July 18, 2011, by and between Kamada Ltd. and Kedrion S.p.A. (incorporated by reference to Exhibit 10.10 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).

4.10	English translation of form of Indemnification Agreement with the Registrant's directors and officers (incorporated by reference to Exhibit 10.15 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.11	English translation of amendment to form of Indemnification Agreement with the Registrant's directors and officers (incorporated by reference to Appendixes A3 and A4 of the Proxy filed as Exhibit 99.1 to Form 6-K filed with the Securities and Exchange Commission on May 22, 2015).
4.12	English summary of two lease agreements dated June 20, 2002, by and between the Israel Lands Administration and Kamada Nehasim (2001) Ltd., as such agreements were amended by lease agreement dated January 30, 2011, by and between the Israel Lands Authority and Kamada Assets (2001) Ltd. (incorporated by reference to Exhibit 10.16 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.13†	Fraction IV-1 Paste Supply Agreement, dated December 3, 2012, by and between Baxter Healthcare S.A. and Kamada Ltd. (incorporated by reference to Exhibit 10.18 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.14	Side Letter Agreement, dated as of March 23, 2011, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.20 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.15	First Amendment to the Exclusive Manufacturing Supply and Distribution Agreement, dated as of September 6, 2012, between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.21 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.16†	Second Amendment to the Exclusive Manufacturing, Supply and Distribution Agreement, dated as of May 14, 2013, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.22 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.17†	First Amendment to the Technology License Agreement, dated as of May 14, 2013, by and between Kamada Ltd. and Baxter Healthcare SA (incorporated by reference to Exhibit 10.23 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 28, 2013).
4.18†	Third Amendment to the Exclusive Manufacturing, Supply and Distribution Agreement, dated as of September 2014, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 4.25 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 28, 2015).
4.19†	Third Amendment to the Amended and Restated Fraction IV-1 Paste Supply Agreement executed on July 19, 2015 by and between Kamada Ltd. and Baxalta U.S. Inc. (incorporated by reference to Exhibit 4.29 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2016).
4.20†	Fourth Amendment to the Exclusive Manufacturing, Supply and Distribution Agreement, dated as of October, 2015, by and between Kamada Ltd. and Baxalta U.S. Inc. (incorporated by reference to Exhibit 4.30 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2016).

4.21†	Second Amendment to the Technology License Agreement, dated as of August 25, 2015, by and between Kamada Ltd. and Baxalta GmbH. (incorporated by reference to Exhibit 4.31 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2016).
4.22†	Fifth Amendment to the Exclusive Manufacturing, Supply and Distribution Agreement, dated as of October 5, 2016, by and between Kamada Ltd. and Shire plc. (incorporated by reference to Exhibit 4.28 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 1, 2017).
4.23	Compensation Policy for Executive Officers (incorporated by reference to Exhibit 4.23 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 15, 2023).
4.24	Compensation Policy for Directors (incorporated by reference to Exhibit 4.24 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 15, 2023).
4.25	Kamada Ltd. 2011 Israeli Share Award Plan (incorporated by reference to Exhibit 4.25 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 15, 2023).
4.26	Kamada Ltd. 2011 Israeli Share Award Plan Appendix – U.S. Taxpayer. (incorporated by reference to Exhibit 4.26 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 15, 2022).
4.27†	1st Addendum to Supply And Distribution Agreement dated October 15, 2016 between Kamada Ltd., and Kedrion S.p.A. (incorporated by reference to Exhibit 4.32 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 1, 2017).
4.28†	2nd Addendum to Supply And Distribution Agreement dated October 11, 2018 between Kamada Ltd., and Kedrion S.p.A. (incorporated by reference to Exhibit 4.29 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 27, 2019).
4.29†	Sixth Amendment to the Exclusive Manufacturing, Supply and Distribution Agreement, dated as of August 30, 2019, by and between Kamada Ltd. and Baxalta U.S. Inc. (incorporated by reference to Exhibit 4.30 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2020).
4.30†	Clinical Study Supply Agreement, dated as of May 5, 2019, by and between PARI GmbH and Kamada Ltd. (incorporated by reference to Exhibit 4.31 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2020).
4.31	Share Purchase Agreement dated as of January 20, 2020, by and among Kamada Ltd. and the FIMI Funds (incorporated by reference to Exhibit 99.2 to Form 6-K filed with the Securities and Exchange Commission on January 21, 2020).
4.32†	Registration Rights Agreement, dated as of January 20, 2020, by and among Kamada Ltd. and the FIMI Funds (incorporated by reference to Exhibit 99.3 to Form 6-K filed with the Securities and Exchange Commission on January 21, 2020).
4.33†	Distribution Agreement, dated as of May 20, 2020, by and between Kamada Ltd. and TUTEUR S.A.C.I.F.I.A. (incorporated by reference to Exhibit 4.33 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 24, 2021)
4.34†	Binding Term Sheet, dated as of April 27, 2020, between Kamada Ltd. and Kedrion S.p.A. (incorporated by reference to Exhibit 4.34 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 24, 2021)
4.35	Asset Purchase Agreement, dated January 31, 2021, by and among Kamada Plasma, LLC and Blood and Plasma Research, Inc (incorporated by reference to Exhibit 4.35 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 24, 2021)
4.36	Asset Purchase Agreement dated November 22, 2021, by and among Saol International Limited, Saol Bermuda Limited, Saol Therapeutics Research Limited, Saol Therapeutics Inc., Saol US Inc., Kamada Limited and Kamada Inc. (incorporated by reference to Exhibit 99.2 to Form 6-K filed with the Securities and Exchange Commission on November 22, 2021).

4.37†	Amended and Restated Manufacturing Services Agreement dated as of September 28, 2017, by and between Emergent BioSolutions, Inc. and Aptevo Therapeutics Inc. (assumed by Kamada Ltd.) (incorporated by reference to Exhibit 4.37 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 15, 2023)
4.38†	Contract Manufacturing, Services and Supply Agreement dated November 29, 2022, by and between Kamada Ltd. and Prothya Biosolutions Belgium (incorporated by reference to Exhibit 4.38 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 15, 2023)
4.39†	Supplemental Letter Agreement dated as of July 4, 2022, by and between Kamada Ltd. and TUTEUR S.A.C.I.F.I.A. (incorporated by reference to Exhibit 4.39 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 15, 2023)
4.40†	2nd Amendment to the Distribution Agreement, dated as of February 22, 2023, by and between Kamada Ltd. and TUTEUR S.A.C.I.F.I.A. (incorporated by reference to Exhibit 4.40 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 15, 2023)
4.41	Share Purchase Agreement dated May 23, 2023, by and among Kamada Ltd., FIMI Opportunity 7, L.P. and FIMI Israel Opportunity 7, Limited Partnership (incorporated by reference to Exhibit 99.2 to Form 6-K filed with the Securities and Exchange Commission on May 24, 2023)
4.42	Amended and Restated Registration Rights Agreement dated May 23, 2023, by and among Kamada Ltd. and the FIMI Funds (incorporated by reference to Exhibit 99.3 to Form 6-K filed with the Securities and Exchange Commission on May 24, 2023)
4.43	Kamada Ltd. Recoupment Policy
4.44†	Memorandum of Understandings dated December 4, 2023, by and among Kamada Ltd., and Kedrion Biopharma Inc. (incorporated by reference to Exhibit 99.2 to Form 6-K filed with the Securities and Exchange Commission on December 6, 2023)
4.45†	3rd Amendment to the Distribution Agreement, dated as of January 18, 2024, by and between Kamada Ltd. and TUTEUR S.A.C.I.F.I.A.
8.1	Subsidiaries of the Registrant.
12.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a)/15d-14(a).
12.2	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a)/15d-14(a).
13.1	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
15.1	Consent of Ernst & Young Global, independent registered public accounting firm.
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

† Portions of this exhibit have been omitted.

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.

KAMADA LTD.

By: /s/ Chaime Orlev
Chaime Orlev
Chief Financial Officer

Date: March 6, 2024

Kamada Ltd. and Subsidiaries

Consolidated Financial Statements as of December 31, 2023

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REPORT OF INDEPENDENCE REGISTERED PUBLIC ACCOUNTING FIRM
To the Shareholders and the Board of Directors of

Kamada Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of Kamada Ltd. and subsidiaries (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of profit or loss and other comprehensive income, consolidated statements of changes in equity, and consolidated statements of cash flows, for each of the three years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standard Board.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 6, 2024 expressed an unqualified opinion thereon.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

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Valuation of Inventory

Description of the Matter	As of December 31, 2023, the Company's inventory totaled $88 million. As described in Note 2 to the consolidated financial statements, inventory is comprised of raw materials, work-in-progress, and finished goods relating to both the Proprietary and Distribution segments. The value of work in progress and finished goods related to the Proprietary Products segment includes direct and indirect costs. As part of the quarterly inventory valuation process, the Company assesses the potential effect on inventory in cases of deviations from quality standards in the manufacturing process to identify potential required inventory write offs. Auditing the valuation of the Company's inventory was complex and involved subjective auditor judgment because of the significant assumptions management makes to determine inventory write-off as a result from deviations from quality standards. Management's determination of deviations from quality standards is based on qualitative assessment, historical data and the Company's past experience.
How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated, and tested the design and operating effectiveness of internal controls over the Company's inventory valuation process, including controls of the assessment of required write offs due to deviations from quality standards, and the completeness and accuracy of underlying data and assumptions. To test management's assessment of required write offs due to deviation from quality standards, our audit procedures included, among others, obtaining the deviations analysis reports from management and evaluating their appropriateness by comparing with historical data. We also held discussions with Company personnel to understand the judgments and qualitative factors considered in their analysis and compared the analysis reports with evidence obtained in other areas of the audit.

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Valuation of goodwill in the proprietary segment

Description of the Matter

As discussed in Note 2d and Note 11 to the consolidated financial statements, as of December 31, 2023, the Company has a goodwill of USD 30 million which is related to the proprietary segment. The Company tests the goodwill for impairment at least annually on December 31 at the single operating segment level (one cash-generating unit (CGU)), which is the level at which goodwill is monitored for internal management purposes. The Company performed a quantitative impairment analysis as of December 31, 2023, estimating the fair value of the proprietary segment by utilizing an income approach that uses the discounted cash flow ("DCF") analysis. As part of the Company's analysis of its goodwill, the results of this test indicated that the estimated fair value exceeded the carrying value as of December 31, 2023.

Auditing the Company's goodwill impairment test was complex due to the significant judgement involved and required the involvement of specialist in determining the fair value of the proprietary segment. In particular, the fair value estimate was sensitive to significant assumptions that require judgment, including the amount and timing of future cash flows (e.g., revenue growth rates and gross margin), long-term growth rates, and the discount rate. These assumptions are affected by factors such as expected future market or economic conditions.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company's goodwill impairment review process. For example, we tested controls over management's review of the valuation model and the significant assumptions, as discussed above, used to develop the prospective financial information. We also tested management's controls to validate that the data used in the valuation was complete and accurate.

To test the estimated fair value of the Company's proprietary segment, we performed audit procedures that included, among others, testing management's process for developing the fair value estimate; evaluating the appropriateness of the discounted cash flow model; testing the completeness, accuracy, and relevance of underlying data used in the model; and evaluating the significant assumptions as mentioned above. Evaluating management's assumptions related to future cash flows involved evaluating whether the assumptions used by management were reasonable considering (i) the current and past performance of the proprietary segment, (ii) the consistency with external market and industry data, (iii) sensitivities over significant inputs and assumptions and (iv) whether these assumptions were consistent with evidence obtained in other areas of the audit. We also involved our valuation specialists in assisting with our evaluation of the methodology used by the Company and the significant assumptions included in the fair value estimates.

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Valuation of the provision of sales rebates, and wholesaler chargebacks liabilities (the "Rebates") in the United States

Description of the Matter

As discussed in Note 2m and Note 3 to the consolidated financial statements, following the acquisition of a portfolio of four FDA-approved plasma derived hyperimmune commercial products (as described under Note 5b), the Company sells these products mainly within the U.S markets through its subsidiary Kamada Inc. to wholesalers/distributors. The Company's gross sales are subject to various deductions, which are primarily composed of rebates to group purchasing organizations, government agencies, wholesalers, health insurance companies and managed healthcare organizations. These rebates represent estimates of the related obligations, requiring the use of judgment when estimating the effect of these rebates on gross sales for a reporting period.

Auditing the provision of the rebates related to the U.S markets is complex because of the subjectivity of certain assumptions and judgments required to develop estimates. These significant assumptions and judgments include consideration of historical claims, experience, payer channel mix, current contract prices, unbilled claims, and claims submissions time lags. Additionally, auditing this matter is challenging given the Company's limited availability of historical sales and rebate data for these products.

How We Addressed the Matter in Our Audit

We evaluated the design and tested the operating effectiveness of certain internal controls over the Company's rebates provision process. We obtained an understanding of the Company's process to estimate the provision for rebates.

We performed substantive test procedures related to the rebates, which included testing the significant assumptions and mathematical accuracy. We tested the completeness of the data used in the estimates and developed expectations of the key inputs using independent sources. To address the completeness of the provision, we also assessed the historical accuracy of management's estimates by comparing actual activity to previous estimates and performing analytical procedures. Finally, we considered subsequent events and any new information after the financial statement date that would require an adjustment to the provision.

/s/ KOST FORER GABBAY & KASIERER
A Member of EY Global

We have served as the Company's auditor since 2005.
Tel-Aviv, Israel
March 6, 2024

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Kamada Ltd.

Opinion on Internal Control Over Financial Reporting

We have audited Kamada Ltd and subsidiaries' internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), (the COSO criteria). In our opinion, Kamada Ltd. and subsidiaries (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Consolidated Statements of Financial Position of the Company as of December 31, 2023 and 2022, the related consolidated statements of profit or loss and other comprehensive income, Consolidated Statements of Changes in Equity and cash flows for each of the three years in the period ended December 31, 2023, and the related notes and our report dated March 6, 2024 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process 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. A 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 receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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.

/s/ KOST FORER GABBAY & KASIERER
A Member of EY Global

Tel-Aviv, Israel
March 6, 2024

Consolidated Statements of Financial Position

	Note	As of December 31, 2023	2022
		U.S. Dollars in thousands	
Assets			
Current Assets			
Cash and cash equivalents	6	$ 55,641	$ 34,258
Trade receivables, net	7	19,877	27,252
Other accounts receivables	8	5,965	8,710
Inventories	9	88,479	68,785
Total Current Assets		169,962	139,005
Non-Current Assets			
Property, plant and equipment, net	10	28,224	26,157
Right-of-use assets	15	7,761	2,568
Intangible assets, Goodwill and other long-term assets	11	140,465	147,072
Contract asset	18e	8,495	7,577
Total Non-Current Assets		184,945	183,374
Total Assets		$ 354,907	$ 322,379
Liabilities			
Current Liabilities			
Current maturities of bank loans	14a	$ -	$ 4,444
Current maturities of lease liabilities	15	1,384	1,016
Current maturities of other long term liabilities	14b	14,996	29,708
Trade payables	12	24,804	32,917
Other accounts payables	13	8,261	7,585
Deferred revenues	18	148	35
Total Current Liabilities		49,593	75,705
Non-Current Liabilities			
Bank loans	14a	-	12,963
Lease liabilities	15	7,438	2,177
Contingent consideration	14b	18,855	17,534
Other long-term liabilities	14b	34,379	37,308
Employee benefit liabilities, net	17	621	672
Total Non-Current Liabilities		61,293	70,654
Shareholder's Equity	20		
Ordinary shares		15,021	11,734
Additional paid in capital net		265,848	210,495
Capital reserve due to translation to presentation currency		(3,490)	(3,490)
Capital reserve from hedges		140	(88)
Capital reserve from share-based payments		6,427	5,505
Capital reserve from employee benefits		275	348
Accumulated deficit		(40,200)	(48,484)
Total Shareholder's Equity		244,021	176,020
Total Liabilities and Shareholder's Equity		$ 354,907	$ 322,379

The accompanying notes are an integral part of the Consolidated Financial Statements.

Consolidated Statements of Profit or Loss and Other Comprehensive Income

	Note	For the Year Ended December 31, 2023	2022	2021
		U.S. Dollars in thousands, except for share and per share data		
Revenues from proprietary products	1a	$ 115,458	$ 102,598	$ 75,521
Revenues from distribution		27,061	26,741	28,121
Total revenues	23a,b	142,519	129,339	103,642
Cost of revenues from proprietary products		63,342	58,229	48,194
Cost of revenues from distribution		23,687	24,407	25,120
Total cost of revenues	23c	87,029	82,636	73,314
Gross profit		55,490	46,703	30,328
Research and development expenses	23d	13,933	13,172	11,357
Selling and marketing expenses	23e	16,193	15,284	6,278
General and administrative expenses	23f	14,381	12,803	12,636
Other expense		919	912	753
Operating income		10,064	4,532	(696)
Financial income	23g	588	91	295
Income (expenses) in respect of currency exchange differences and derivatives instruments, net	23g	55	298	(207)
Revaluation of long-term liabilities	16	(980)	(6,266)	(994)
Financial expense	23g	(1,298)	(914)	(283)
Income before tax on income		8,429	(2,259)	(1,885)
Taxes on income	22	145	62	345
Net Income (Loss)		$ 8,284	(2,321)	$ (2,230)
Other Comprehensive Income:				
Amounts that will be or that have been reclassified to profit or loss when specific conditions are met				
Gain (loss) on cash flow hedges		(186)	(776)	-
Net amounts transferred to the statement of profit or loss for cash flow hedges		414	634	(303)
Items that will not be reclassified to profit or loss in subsequent periods:				
Remeasurement gain (loss) from defined benefit plan		(73)	497	171
Total comprehensive income (loss)		$ 8,439	$ (1,966)	$ (2,362)
Earnings per share attributable to equity holders of the Company:	24			
Basic net earnings (loss) per share		$ 0.17	$ (0.05)	$ (0.05)
Diluted net earnings per (loss) share		$ 0.15	$ (0.05)	$ (0.05)

The accompanying notes are an integral part of the Consolidated Financial Statements.

Consolidated Statements of Changes in Equity

	Share capital	Additional paid in capital	Capital reserve due to translation to presentation currency	Capital reserve from hedges	Capital reserve from share based payments	Capital reserve from employee benefits	Accumulated deficit	Total equity
	U.S. Dollars in thousands							
Balance as of December 31, 2020	$11,706	$ 209,760	$ (3,490)	$ 357	$ 4,558	$ (320)	$ (43,933)	$178,638
Net income (loss)							(2,230)	(2,230)
Other comprehensive income (loss)	-	-	-	(303)	-	171	-	(132)
Total comprehensive income (loss)	-	-	-	(303)	-	171	(2,230)	(2,362)
Exercise and forfeiture of share-based payment into shares	19	444	-	-	(444)	-	-	19
Cost of share-based payment	-	-	-	-	529	-	-	529
Balance as of December 31, 2021	$11,725	210,204	$ (3,490)	54	4,643	$ (149)	$ (46,163)	$176,824
Net income (loss)							(2,321)	(2,321)
Other comprehensive income (loss)	-	-	-	(142)	-	497	-	355
Total comprehensive income (loss)	-	-	-	(142)	-	497	(2,321)	(1,966)
Exercise and forfeiture of share-based payment into shares	9	291	-	-	(291)	-	-	9
Cost of share-based payment	-	-	-	-	1,153	-	-	1,153
Balance as of December 31, 2022	$11,734	210,495	$ (3,490)	(88)	5,505	$ 348	$ (48,484)	$176,020
Net income (loss)							8,284	8,284
Other comprehensive income (loss)	-	-	-	228	-	(73)	-	155
Total comprehensive income (loss)	-	-	-	228	-	(73)	8,284	8,439
Issuance of shares	3,283	54,948						58,231
Exercise and forfeiture of share-based payment into shares	4	405			(405)			4
Cost of share-based payment	-	-	-	-	1,327	-	-	1,327
Balance as of December 31, 2023	$15,021	$ 265,848	$ (3,490)	$ 140	$ 6,427	$ 275	$ (40,200)	$244,021

The accompanying notes are an integral part of the Consolidated Financial Statements.

Consolidated Statements of Cash Flows

	Note	For the year ended December 31, 2023	2022	2021
		U.S. Dollars in thousands		
Cash Flows from Operating Activities				
Net (loss) income		$ 8,284	$ (2,321)	$ (2,230)
Adjustments to reconcile net income to net cash (used in) provided by operating activities:				
Adjustments to the profit or loss items:				
Depreciation and amortization	10,11	12,714	12,155	5,609
Financial expense (income), net		1,635	6,791	1,189
Cost of share-based payment	20	1,314	1,153	529
Taxes on income	22	145	62	345
Gain from sale of property and equipment		(5)	-	-
Change in employee benefit liabilities, net		(125)	(111)	45
		15,678	20,050	7,717
Changes in asset and liability items:				
Decrease (increase) in trade receivables, net		7,835	7,603	(12,861)
Increase in other accounts receivables		(1,150)	(578)	(1,634)
Increase in inventories		(19,694)	(1,361)	(2,373)
Decrease (increase) in deferred expenses		2,814	(1,340)	(6,883)
Increase (decrease) in trade payables		(8,885)	7,055	7,917
Increase (decrease) in other accounts payables		765	290	(392)
Increase (decrease) in deferred revenues		113	(20)	1,815
		(18,202)	11,649	(14,411)
Cash paid during the year for:				
Interest paid		(1,228)	(853)	(228)
Interest received		-	97	375
Taxes paid		(217)	(36)	(42)
		(1,445)	(792)	105
Net cash (used in) provided by operating activities		$ 4,315	$ 28,586	$ (8,819)

The accompanying notes are an integral part of the Consolidated Financial Statements.

Consolidated Statements of Cash Flows

	Note	For the year ended December 31, 2023	2022	2021
		U.S. Dollars in thousands		
Cash Flows from Investing Activities				
Investment in short term investments, net		$ -	$ -	$ 39,083
Purchase of property and equipment and intangible assets	9	(5,850)	(3,784)	(3,730)
Business combination			-	(96,403)
Proceeds from sale of property and equipment		7	-	-
Net cash used in investing activities		(5,843)	(3,784)	(61,050)
Cash Flows from Financing Activities				
Proceeds from exercise of share base payments		4	9	19
Receipt of long-term loans		-	-	20,000
Proceeds from issuance of ordinary shares, net	20f	58,231	-	-
Repayment of lease liabilities		(850)	(1,098)	(1,221)
Repayment of long-term loans		(17,407)	(2,628)	(205)
Repayment of other long-term liabilities		(17,300)	(5,626)	-
Net cash provided by (used in) financing activities		22,678	(9,343)	18,593
Exchange differences on balances of cash and cash equivalent		233	212	(334)
Increase (decrease) in cash and cash equivalents		21,383	15,671	(51,610)
Cash and cash equivalents at the beginning of the year		34,258	18,587	70,197
Cash and cash equivalents at the end of the year		$ 55,641	$ 34,258	$ 18,587
Significant non-cash transactions				
Right-of-use asset recognized with corresponding lease liability	15	$ 6,546	$ 551	$ 845
Purchase of property and equipment		$ 646	$ 618	$ 1,001

The accompanying notes are an integral part of the Consolidated Financial Statements.

NOTE 1: - GENERAL

a. General description of the Company and its activity

Kamada Ltd. (the "Company") is a commercial stage global biopharmaceutical company with a portfolio of marketed products indicated for rare and serious conditions and a leader in the specialty plasma-derived field focused on diseases of limited treatment alternatives. The Company is also advancing an innovative development pipeline targeting areas of significant unmet medical need. The Company's strategy is focused on driving profitable growth from its significant commercial catalysts as well as its manufacturing and development expertise in the plasma-derived and biopharmaceutical fields. The Company's commercial products portfolio includes six FDA approved plasma-derived biopharmaceutical products KEDRAB®, CYTOGAM®, VARIZIG®, WINRHO SDF®, HEPAGAM B® and GLASSIA®, as well as KAMRAB®, KAMRHO (D)® and two types of equine-based anti-snake venom (ASV) products. The Company distributes its commercial products portfolio directly, and through strategic partners or third-party distributors in more than 30 countries, including the U.S., Canada, Israel, Russia, Argentina, Brazil, India, Australia and other countries in Latin America, Europe, the Middle East and Asia. The Company leverages its expertise and presence in the Israeli market to distribute, for use in Israel, more than 25 pharmaceutical products that are supplied by international manufacturers and in addition have eleven biosimilar products in its Israeli distribution portfolio, which, subject to European Medicines Agency (EMA) and Israeli Ministry of Health ("IL MOH") approvals, are expected to be launched in Israel through 2028. The Company owns an FDA licensed plasma collection center in Beaumont, Texas, which currently specializes in the collection of hyper-immune plasma used in the manufacture of KAMRHO (D), KAMRAB and KEDRAB. In addition to the Company's commercial operation, it invests in research and development of new product candidates. The Company's leading investigational product is an inhaled AAT for the treatment of AAT deficiency, for which it is continuing to progress the InnovAATe clinical trial, a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial.

In November 2021, the Company entered into an Assets Purchase Agreement with Saol Therapeutics Ltd. ("Saol" and the "Saol APA") for the acquisition of CYTOGAM, WINRHO SDF, VARIZIG and HEPGAM B (collectively the "Four FDA-Approved Plasma Derived Hyperimmune Commercial Products"). The acquisition of this portfolio furthered the Company's core objective to become a fully integrated specialty plasma company with strong commercial capabilities in the U.S. market, as well as to expand to new markets, mainly in the Middle East/North Africa region, and to broaden the Company's portfolio offering in existing markets. The Company's wholly owned U.S. subsidiary, Kamada Inc., is responsible for the commercialization of the four products in the U.S. market, including direct sales to wholesalers and local distributers. Refer to Note 5 for further details on this acquisition.

The Company markets GLASSIA in the U.S. through a strategic partnership with Takeda Pharmaceuticals Company Limited ("Takeda"). Through 2021, the Company generated revenues on sales of GLASSIA, manufactured by the Company, to Takeda for further distribution in the United States. In accordance with the agreement with Takeda, the Company ceased the production and sale of GLASSIA to Takeda during 2021, and during the first quarter of 2022, Takeda began to pay the Company royalties on sales of GLASSIA manufactured by Takeda, at a rate of 12% on net sales through August 2025 and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually for each year from 2022 to 2040. Refer to Note 18 for further details on the engagement with Takeda.

NOTE 1: - GENERAL (CONT.)

The Company's activity is divided into two operating segments:

Proprietary Products	Development, manufacturing, sales and distribution of plasma-derived protein therapeutics.
Distribution	Distribute imported drug products in Israel, which are manufactured by third parties.

The Company's ordinary shares are listed for trading on the Tel Aviv Stock Exchange and the NASDAQ Global Select Market.

FIMI Opportunity Funds ("FIMI"), the leading private equity firm in Israel beneficially owns approximately 38% of the Company's outstanding ordinary shares and is a controlling shareholder of the Company; within the meaning of the Israeli Companies Law, 1999. Refer to Note 20 for further details and Item 7 within the Company annual reports on Form 20-F.

The Company has four wholly-owned subsidiaries – Kamada Inc., Kamada Plasma LLC (wholly owned by Kamada Inc.), KI Biopharma LLC and Kamada Ireland Limited. In addition, the Company owns 74% of Kamada Assets Ltd. ("Kamada Assets").

b. Definitions

In these Financial Statements –

The Company	-	Kamada Ltd.
The Group	-	The Company and its subsidiaries.
Subsidiary	-	A company which the Company has a control over (as defined in IFRS 10) and whose financial statements are consolidated with the Company's Financial Statements.
Related parties	-	As defined in International Accounting Standard ("IAS") 24.
USD/$	-	U.S. dollar.
NIS	-	New Israeli Shekel
EUR	-	Euro

NOTE 2: - MATERIAL ACCOUNTING POLICIES

a. Basis of presentation of financial statements

1. These financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standard Board.

2. Measurement basis:

The Company's consolidated financial statements are prepared on a cost basis, except for financial assets and liabilities (including derivatives and contingent consideration) which are measured at fair value through profit or loss (See Note 16).

The Company has elected to present profit or loss items using the "function of expense" method.

b. The Company's operating cycle is one year.

c. Functional currency, presentation currency and foreign currency

1. Functional currency and presentation currency

The consolidated financial statements are presented in U.S. dollars, which is the Company's functional and presentation currency.

2. Transactions, assets and liabilities in foreign currency

Transactions denominated in foreign currency are recorded on initial recognition at the exchange rate at the date of the transaction. After initial recognition, monetary assets and liabilities denominated in foreign currency are translated at the end of each reporting period into the functional currency at the exchange rate at that date. Exchange differences are recognized in profit or loss. Non-monetary assets and liabilities measured at cost in a foreign currency are translated at the exchange rate at the date of the transaction.

d. Business combinations and goodwill:

In November 2021, the Company acquired the Four FDA-Approved Plasma Derived Hyperimmune Commercial Products from Saol, see Note 1(a). The acquisition was accounted for as a business combination, for which a key element of the consideration was contingent.

The contingent consideration was recognized at fair value on the acquisition date and classified as a financial liability in accordance with IFRS 9.

Contingent consideration is measured at fair value. The fair value is determined using valuation techniques and method, using future cash flows discounted. Subsequent changes in the fair value of the contingent consideration are recognized in profit or loss as finance income or finance expense.

As part of the acquisition, the Company also assumed certain of Saol's liabilities for the future payment of royalties (some of which are perpetual) and milestone payments to third party subject to the achievement of corresponding CYTOGAM related net sales. Such assumed liabilities were accounted for as a financial liability on the acquisition date. Subsequently, the financial liability is measured at amortized cost, per IFRS 9. Remeasurement of the financial liability is recognized as finance income or expense in the statement of operations.

Refer to Note 5 and Note 16 for further information.

Goodwill is initially measured at cost which represents the excess of the acquisition consideration over the net identifiable assets acquired and liabilities assumed. At each reporting date, the Company reviews the carrying amount of the goodwill to determine whether there is any indication of impairment.

NOTE 2: - MATERIAL ACCOUNTING POLICIES (CONT.)

e. Inventories

Inventories are measured at the lower of cost and net realizable value. The cost of inventories comprises of the costs of purchase of raw and other materials and costs incurred in bringing the inventories to their present location and condition. Net realizable value is the estimated selling price in the ordinary course of business.

Cost of inventories is determined as follows:

Raw materials	At cost using the first-in, first-out method.
Work in process	Costs of raw materials, direct and indirect costs including labor, other materials and other indirect manufacturing costs allocated to the in process manufactured batches through the end of the reporting period. The allocation of indirect costs is accounted for on a quarterly basis by dividing the total quarterly indirect manufacturing cost to the batches manufactured during that quarter based on predetermined allocation factors. The Company determines a standard manufacturing capacity for each quarter. To the extent the actual manufacturing capacity in a given quarter is lower than the predetermined standard, than a portion of the indirect costs which is equal to the product of the overall quarterly indirect costs multiplied by the quarterly manufacturing shortfall rate is recognized as costs of revenues
Finished products	Costs of raw materials, direct and indirect costs including labor, other materials and other indirect manufacturing costs allocated to the manufactured finished products through completion of manufacturing process.
Purchased products	At cost using the first-in, first-out method.

The Company periodically evaluates the condition and age of inventories and accounts for impairment of inventories with a lower market value or which are slow moving.

f. Financial instruments

1 Financial assets

The Company's portfolio of financial assets consists mainly of trade receivables and bank deposits. The objective of the business model for managing the Company's financial instruments is to collect the amounts due from them, and for bank deposits to earn contractual interest income on the amounts collected. All of the Company's financial assets' contractual cash flows represent solely payments of principal and interest (SPPI). Thus, the Company accounts for its financial assets under the amortized cost model. For those financial assets, the Company analyzes each material customer's balance individually to evaluate and measure the expected credit losses ("ECLs") of its trade receivables. Loss rates are based on actual credit loss experience, adjusted for current conditions and the Company's view of the economic conditions over the expected lives of the trade receivables

NOTE 2: - MATERIAL ACCOUNTING POLICIES (CONT.)

2. Financial liabilities

Financial liabilities within the scope of IFRS 9 are initially measured at fair value less transaction costs that are directly attributable to the issuance of the financial liability.

After initial recognition, the accounting treatment of financial liabilities is based on their classification as follows:

a) Financial liabilities measured at amortized cost

Loans and assumed liabilities are measured based on their terms at amortized cost using the effective interest method taking into account directly attributable transaction costs.

b) Financial liabilities measured at fair value

Derivatives are classified as fair value through profit and loss unless they are designated as effective hedging instruments (see below). Transaction costs are recognized in profit or loss.

After initial recognition, changes in fair value are recognized either in income (expenses) in respect of currency exchange differences and derivatives instruments line item for non-hedge accounting derivatives or in other comprehensive income for hedge accounting derivatives.

For accounting for contingent consideration, see Note 2(d).

g. Derivative financial instruments designated as hedges

The Company enters into contracts for derivative financial instruments such as forward currency contracts and cylinder strategy in respect of foreign currency to hedge risks associated with foreign exchange rates fluctuations and cash flows risk. Such derivative financial instruments are carried as financial assets when the fair value is positive and as financial liabilities when the fair value is negative.

At the inception of a hedge relationship, the Company formally designates and documents the hedge relationship to which the Company wishes to apply hedge accounting and the risk management objective and strategy for undertaking the hedge. The hedge effectiveness is assessed at the end of each reporting period.

Any gains or losses arising from changes in the fair value of derivatives that do not qualify for hedge accounting are recorded in profit or loss.

Cash flow hedges

The effective portion of the gain or loss on the hedging instrument is recognized as other comprehensive income (loss), while any ineffective portion is recognized immediately in profit or loss.

Amounts recognized as other comprehensive income (loss) are reclassified to profit or loss when the hedged transaction affects profit or loss, such as when the hedged income or expense is recognized or when a forecast payment occurs.

h. Property, plant and equipment

Property, plant and equipment are measured at cost, including directly attributable costs, less accumulated depreciation and any related investment grants and excluding day-to-day servicing expenses. Cost includes spare parts and auxiliary equipment that can be used only in connection with the plant and equipment.

The cost of assets includes the cost of materials, direct labor costs, as well as any costs directly attributable to bringing the asset to the location and condition necessary for it to operate in the manner intended by management.

The Company's assets include computer systems comprising hardware and software. Software forming an integral part of the hardware to the extent that the hardware cannot function without the software installed on it is classified as property, plant and equipment.

NOTE 2: - MATERIAL ACCOUNTING POLICIES (CONT.)

Depreciation is calculated on a straight-line basis over the useful life of the assets at annual rates as follows:

	%	Mainly %
Buildings	2.5-4	4
Machinery and equipment	10-20	15
Vehicles	15	15
Computers, software, equipment and office furniture	6-33	33
Leasehold improvements	(*)	10

(*) Leasehold improvements are depreciated on a straight-line basis over the shorter of the lease term (including the extension option held by the Company and intended to be exercised) and the expected life of the improvement.

i. Leases

The Company enters into leases of office including facility dedicated for the plasma collection centers and storage spaces, vehicles, office equipment and lands as a lessee (see Note 15).

For leases in which the Company is the lessee, the Company recognizes on the commencement date of the lease a right-of-use asset and a lease liability, excluding leases whose term is up to 12 months and leases for which the underlying asset is of low value. For these excluded leases, the Company has elected to recognize the lease payments as an expense in profit or loss on a straight-line basis over the lease term. In measuring the lease liability, the Company has elected to apply the practical expedient and does not separate the lease components from the non-lease components (such as management and maintenance services, etc.).

On the commencement date, the lease liability includes all unpaid lease payments discounted at the interest rate implicit in the lease, if that rate can be readily determined, or otherwise using the Company's incremental borrowing rate. The Company determines the incremental borrowing rate based on its credit risk, the lease term and other economic variables deriving from the lease contract's conditions and restrictions. In certain situations, the Company is assisted by an external valuation expert in determining the incremental borrowing rate. After the commencement date, the Company measures the lease liability using the effective interest rate method.

The right-of-use asset is measured applying the cost model and depreciated over the shorter of its useful life or the lease term, as follows:

	%	Mainly %
Land and Buildings	5-10	10
Vehicles	20-33	33
office equipment (i.e. printing and photocopying machines)	20	20

Lease modification:

Most of the Company's lease modifications are for the extension of existing lease contracts. Thus, they do not reduce the scope of the lease or result in a separate lease. Under those modifications, the Company re-measures the lease liability based on the modified lease terms using a revised discount rate as of the modification date and records the change in the lease liability as an adjustment to the right-of-use asset.

j. Intangible assets

Separately acquired intangible assets are measured on initial recognition at cost including directly attributable costs. Intangible assets acquired in a business combination are measured at fair value at the acquisition date.

NOTE 2: - MATERIAL ACCOUNTING POLICIES (CONT.)

Intangible assets with a finite useful life are amortized on a straight-line basis over their useful life, as follows:

	Estimated life	Amortization method
Intellectual property	15-20	Straight-line
Customer Relations	20	Straight-line
Production agreement	6	Straight-line
Distribution right	10-15	Straight-line over the contract period
Goodwill	Indefinite	Not amortized

For additional information regarding intangible assets, see Note 11.

k. Impairment of non-financial assets

At each reporting date, the Company reviews the carrying amount of non-financial assets (other than inventories, contract assets and deferred tax assets) to determine whether there is any indication of impairment. If any such indication exists, then the assets' recoverable amount is estimated. Goodwill is tested annually for impairment on December 31 or more frequently if events or changes in circumstances indicate that there is an impairment. The Company's goodwill is attributed to the Proprietary Products segment, which represents the lowest level within the Company at which goodwill is monitored for internal management purposes (see Note 11).

Goodwill is tested for impairment by assessing the recoverable amount of the CGU (or group of CGUs) to which the goodwill has been allocated. An impairment loss is recognized if the recoverable amount of the CGU (or group of CGU to which goodwill has been allocated is less than the carrying amount of the CGU (or group of CGUs). Any impairment loss is allocated first to goodwill. Impairment losses recognized for goodwill cannot be reversed in subsequent periods.

In the years ended December 31, 2023, and 2022, the Company did not recognize impairment losses.

l. Employee benefit liabilities

The Company has several employee benefit plans:

1. Short-term employee benefits

Short-term employee benefits include salaries, paid annual leave, paid sick leave, recreation, and social security contributions are recognized as expenses as the services are rendered. A liability in respect of a cash bonus is recognized when the Company has a legal or constructive obligation to make such payment as a result of past service rendered by an employee and a reliable estimate of the amount can be made.

2. Post-employment benefits

The post-employment benefits plans are normally financed by contributions to insurance companies and classified as defined contribution plans or as defined benefit plans.

With respect to its employees in Israel, the Company has defined contribution plans pursuant to Section 14 to the Israeli Severance Pay Law, 1963 (the "Israeli Severance Pay Law"), under which the Company pays fixed contributions to certain employees under Section 14 and will have no legal or constructive obligation to pay further contributions.

Contributions to the defined contribution plan in respect of severance or retirement pay are recognized as an expense when contributed concurrently with performance of the employee's services.

NOTE 2: - MATERIAL ACCOUNTING POLICIES (CONT.)

In addition, with respect to certain other employees who were hired by the Company prior to the establishment of the defined contribution plans pursuant to Section 14 to the Israeli Severance Pay Law, the Company operates a defined benefit plan in respect of severance pay pursuant to the Israeli Severance Pay Law. According to the Israeli Severance Pay Law, employees are entitled to severance pay upon dismissal or retirement. The liability for termination of employment is measured using the projected unit credit method. The actuarial assumptions include expected salary increases and rates of employee's turnover based on the estimated timing of payment. The amounts are presented based on discounted expected future cash flows using a discount rate determined by reference to market yields at the reporting date on high quality corporate bonds that are linked to the Consumer Price Index with a term that is consistent with the estimated term of the severance pay obligation.

In respect of its defined benefit plan obligation, the Company makes current deposits in pension funds and insurance companies ("plan assets"). Plan assets comprise assets held by a long-term employee benefit fund or qualifying insurance policies. Plan assets are not available to the Company's own creditors and cannot be returned directly to the Company. The liability for employee benefits shown in the statement of financial position reflects the present value of the defined benefit obligation less the fair value of the plan assets.

U.S. employees defined contribution plan:

Since August 2022, the Company's U.S. subsidiary has a 401(k) defined contribution plan covering certain employees in the U.S. All eligible employees may elect to contribute up to 100% of their annual compensation to the plan through salary deferrals, subject to Internal Revenue Service limits. For the year ended December 31, 2023, the contribution limit was $22,500 per year (for certain employees over 50 years of age the maximum contribution was $30,000 per year). The U.S. subsidiary matches 3% of employee contributions to the plan with no limitation.

m. Revenue recognition

The Company's main source of revenue is from the sale of products to strategic partners and distributors. Starting from 2022, the Company also generates revenue in the form of royalties received under license agreement that grant the use of the Company's knowledge and patents. Under the royalty exception, revenue is recognized when the underlying sales have occurred.

On the contract's inception date the Company assesses the goods or services promised in the contract with the customer and identifies the performance obligations in it. In order to identify distinct performance obligations in a contract with a customer, the Company examines whether it is providing a significant service of integrating the goods or services in the contract into one integrated outcome.

The Company identifies the performance obligations when the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and the Company promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. The Company recognizes revenue from contracts with customers when the control over the goods or services is transferred to the customer.

Revenue recognition occurs at a point in time when control of the Company's product is transferred to the customer, generally on delivery of the goods according to the shipment terms.

The Company determines the transaction price separately for each contract with a customer taking into consideration variable prices, discounts, chargeback, rebates, adjustments to the net market price etc. The Company includes the estimated variable consideration in the transaction price only to the extent it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty is resolved.

NOTE 2: - MATERIAL ACCOUNTING POLICIES (CONT.)

Following the acquisition of the Four FDA-Approved Plasma Derived Hyperimmune Commercial Products during November 2021, the Company, through its wholly-owned subsidiary Kamada Inc., sells these products in the U.S. market to wholesalers/distributors that redistribute/sell these products to other parties such as hospitals and pharmacies. Revenue recognition occurs at a point in time when control of the product is transferred to the wholesalers/distributors, generally on delivery of the goods.

The Company's gross sales are subject to various deductions, which are primarily composed of rebates and discounts to group purchasing organizations, government agencies, wholesalers, health insurance companies and managed healthcare organizations. These deductions represent estimates of the related obligations, requiring the use of judgment when estimating the effect of these sales deductions on gross sales for a reporting period. These adjustments are deducted from gross sales to arrive at net sales. The Company monitors the obligation for these deductions on at least a quarterly basis and records adjustments when rebate trends, rebate programs and contract terms, legislative changes, or other significant events indicate that a change in the obligation is appropriate.

The following summarizes the nature of the most significant adjustments to revenues generated from the sales of these products in the U.S. market:

- Wholesaler chargebacks:

  The Company has arrangements with certain indirect customers whereby the customer is able to buy products from wholesalers at reduced prices. A chargeback represents the difference between the invoice price to the wholesaler and the indirect customer's contractual discounted price. Provisions for estimating chargebacks are calculated based on historical experience and product demand. The provision for chargebacks are recorded as a deduction from trade receivables on the consolidated statements of financial position.

- Fees for service:

  Consists of wholesaler/distributor fees. The wholesalers/distributors charge the Company fees for the redistribution of the products to hospitals and pharmacies. These fees are outlined in each wholesaler/distributor contract. The fees are invoiced to the Company monthly or quarterly by the wholesaler/distributor. The provisions for fees for service are recorded in the same period that the corresponding revenues are recognized.

Costs to fulfill a contract:

Costs to fulfill a contract, which primarily consist of costs arising from technology transfers in preparation of supply contracts or anticipated contracts, are recognized as an asset when the costs generate or enhance the Company's resources that will be used in satisfying or continuing to satisfy the performance obligations in the future and are expected to be recovered. Costs to fulfill a contract consist of direct identifiable costs and indirect costs that can be attributed to a contract based on a reasonable allocation method. These costs include mainly salaries and other employee benefits costs. Costs to fulfill a contract are amortized on a systematic basis that is consistent with the provision of the goods and services under the contracts.

NOTE 2: - MATERIAL ACCOUNTING POLICIES (CONT.)

As of December 31, 2023, and 2022, the Company recognized an asset related to the costs to fulfill a contract in the net amounts of $8,495 thousand and $7,577 thousand, respectively. The Company amortizes the contract asset over an 18-year period straight line basis, representing the expected duration of the relationship with the customer.

In 2023, the Company recognized $51 thousand in amortization costs, which were included in the cost of goods sold. No impairment losses were recognized. Refer to Note 18e for further information.

n. Research and development costs

Research and development expenditures are recognized in profit or loss when incurred and include preclinical and clinical costs (as well as cost of materials associated with the development of new products or existing products for new therapeutic indications). In addition, these costs include additional product development activities with respect to approved and distributed products as well as post marketing commitment research and development activities.

Since the Company's development projects are often subject to regulatory approval procedures and other uncertainties, the conditions for the capitalization of costs incurred before receipt of approvals are not normally satisfied and therefore, development expenditures are recognized in profit or loss when incurred.

o. Taxes on income

Current and Deferred taxes

Taxes on income in profit or loss comprise of current taxes, deferred taxes and taxes in respect of prior years, which are mainly recognized in profit or loss.

Deferred tax assets are reviewed at the end of each reporting period and reduced to the extent that it is not probable that they will be utilized. Deductible carryforward losses and temporary differences for which deferred tax assets had not been recognized are reviewed at the end of each reporting period and a respective deferred tax asset is recognized to the extent that their utilization is probable.

The Company operates in multiple tax jurisdictions. Deferred taxes are offset in the statement of financial position if there is a legally enforceable right to offset a current tax asset against a current tax liability and the deferred taxes relate to the same taxpayer and the same taxation authority.

As of December 31, 2023, the Company did not record deferred tax asset for the remaining carry forward losses due to estimation that their utilization in the foreseeable future is not probable.

Uncertain tax positions

The Company evaluates potential uncertain tax positions, including additional tax and interest expenses, and recognizes a provision when it is more probable than not that the Company will have to use its economic resources to pay the such obligation.

As of December 31, 2023 and 2022, the application of IFRIC 23 did not have a material effect on the financial statements.

NOTE 2: - MATERIAL ACCOUNTING POLICIES (CONT.)

p. Provisions

A provision in accordance with IAS 37 is recognized when the Company has a present (legal or constructive) obligation as a result of a past event, it is expected to require the use of economic resources to clear the obligation and a reliable estimate can be made of it.

q. Share-based payment transactions

The Company's employees and members of its Board of Directors are entitled to remuneration in the form of equity-settled share-based payment transactions, primarily in the form of options and restricted shares units. The cost of equity-settled transactions (options and restricted share units) with employees and members of the Board of Directors is measured at the fair value of the equity instruments granted at grant date. The fair value of options is determined using a standard option pricing model, the binomial option valuation model. The fair value of restricted share is determined using the share price at the grant date.

The cost of equity-settled share-based payments transactions is recognized in profit or loss together with a corresponding increase in shareholder's equity during the period which the performance and/or service conditions are to be satisfied ending on the date on which the relevant employees or directors become entitled to the award ("the vesting period"). The cumulative expense recognized for equity-settled transactions at the end of each reporting period until the vesting date reflects the extent to which the vesting period has expired and the Company's best estimate of the number of equity instruments that will ultimately vest.

No expense is recognized for awards that do not ultimately vest.

NOTE 3: - SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS USED IN THE PREPARATION OF THE FINANCIAL STATEMENTS

a. Judgments

In the process of applying the significant accounting policies, the Company has made the following judgments which have the most significant effect on the amounts recognized in the financial statements:

- Determining the fair value of share-based payment transactions

  The fair value of equity settled share-based payment transactions is determined upon initial recognition by an acceptable option pricing model. The inputs to the model include share price, exercise price (if applicable) and assumptions regarding expected volatility, expected life of the equity instrument and expected dividend yield.

- Revenue

  Identification of performance obligations in contracts with customers:

  In order to identify distinct performance obligations in a contract with a customer, the Company uses judgment when it examines whether it is providing a significant service of integrating the goods or services in the contract into one integrated outcome.

  Measurement of variable consideration

  In order to determine the transaction price, the Company estimates the amount of the variable consideration and recognizes revenue in an amount where there is a high probability that its inclusion will not result in a significant revenue reversal in the future after the uncertainty has been resolved. Following the acquisition of a portfolio of Four FDA-Approved Plasma Derived Hyperimmune Commercial Products (as described under Note 5b), the Company sells its products mainly in the U.S market through its subsidiary Kamada Inc. to wholesalers/distributors. The Company's gross sales are subject to various deductions, which are primarily composed of rebates and discounts to group purchasing organizations, government agencies, wholesalers, health insurance companies and managed healthcare organizations. These deductions represent estimates of the related obligations, requiring the use of judgment when estimating the effect of these sales deductions on gross sales for a reporting period.

  Costs to fulfill a contract:

  Costs fulfill contracts or anticipated contracts with customers are recognized as an asset when the costs generate or enhance the Company's resources that will be used in satisfying or continuing to satisfy the performance obligations in the future and are expected to be recovered. Costs to fulfill a contract consist of direct identifiable costs and other costs that can be directly attributed to a contract based on a reasonable allocation method. Costs to fulfill a contract are amortized on a systematic basis that is consistent with the provision of the services under the specific contract.

NOTE 3: - SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS USED IN THE PREPARATION OF THE FINANCIAL STATEMENTS (CONT.)

- Inventory

  Work in process and finished goods includes direct and indirect costs. The allocation of indirect costs is accounted for on a quarterly basis by dividing the total quarterly indirect manufacturing cost to the batches manufactured during that quarter based on predetermined allocation factors. The criteria for allocation of indirect manufacturing expense to manufactured batches which eventually effect the Company's inventory value is subject to Company judgment.

- Impairment of inventories with realizable value lower than cost or which are slow moving

  Inventories are measured at the lower of cost and net realizable value. The cost of inventories comprises costs of purchase of raw and other materials and costs incurred in bringing the inventories to their present location and condition. Net realizable value is the estimated selling price in the ordinary course of business, net of selling expenses. The estimation of realizable value can affect the inventory value at the period end.

  In addition, and as part of the quarterly inventory valuation process, the Company assesses the potential effect on inventory in cases of deviations from quality standards in the manufacturing process to identify potential required inventory write offs. Such assessment is subject to Company's judgment.

- Inventory designated for R&D activities

  The Company recognizes inventory produced for commercial sale, including costs incurred prior to regulatory approval but subsequent to the filing of a regulatory request when the Company has determined that the inventory has probable future economic benefit. Inventory is not recognized prior to completion of a phase III clinical trial. For products with an approved indication, raw materials and purchased drug product associated with development programs are included in inventory and charged to research and development expense when it is designated. For products without an approved indication, drug product is charged to research and development expenses.

- Lease extension and/or termination options

  In evaluating whether it is reasonably certain that the Company will exercise an option to extend a lease or not exercise an option to terminate a lease, the Company considers all relevant facts and circumstances that create an economic incentive for the Company to exercise the option to extend or not exercise the option to terminate such as: significant amounts invested in leasehold improvements, the significance of the underlying asset to the Company's operation and whether it is a specialized asset, the Company's past experience with similar leases, etc.

  After the commencement date, the Company reassesses the term of the lease upon the occurrence of a significant event or a significant change in circumstances that affects whether the Company is reasonably certain to exercise an option or not exercise an option previously included in the determination of the lease term, such as significant leasehold improvements that had not been anticipated on the lease commencement date, sublease of the underlying asset for a period that exceeds the end of the previously determined lease period, etc.

NOTE 3: - SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS USED IN THE PREPARATION OF THE FINANCIAL STATEMENTS (CONT.)

- Recognition of deferred tax asset in respect of carry forward tax losses

  Deferred tax assets are recognized for unused carryforward tax losses and deductible temporary differences to the extent that it is probable that taxable profit will be available against which the losses can be utilized. Significant management judgment is required to determine the amount of deferred tax assets that can be recognized, based upon the timing and level of future taxable profits, its source and the tax planning strategy. For information regarding deferred taxes recognition, please refer to Note 22.

- Determining cash-generating units

  Impairment testing for assets that cannot be tested individually are grouped together into the smallest group of assets that generates cash inflows from continuing use that are largely independent of the cash inflows of other assets or groups of assets (the "CGU").

  For the purpose of goodwill impairment testing, the Company aggregates CGUs so that the level at which impairment testing is performed reflects the lowest level at which goodwill is monitored for internal reporting purposes. When goodwill is not monitored for internal reporting purposes, it is allocated to operating segments and not to a CGU (or group of CGUs) lower in level than an operating segment. Goodwill acquired in a business combination is allocated to groups of CGUS, including CGUs existing prior to the business combination, that are expected to benefit from the synergies of the combination. Also refer to Note 11.

- Impairment of Company's non-financial assets

  The carrying amounts of the Company's non-financial assets are reviewed at each reporting date to determine whether there is any indication of impairment. If any such indication exists, then the asset's recoverable amount is estimated.

b. Estimates and assumptions

The preparation of the financial statements requires management to make estimates and assumptions that have an effect on the application of the accounting policies and on the reported amounts of assets, liabilities, revenues and expenses. Changes in accounting estimates are reported in the period of the change in estimate.

The key assumptions made in the financial statements concerning uncertainties at the end of the reporting period and the critical estimates computed by the Company that may result in a material adjustment to the carrying amounts of assets and liabilities within the next financial year are discussed below.

- Pensions and other post-employment benefits

  The liability in respect of post-employment defined benefit plans is determined using actuarial valuations. The actuarial valuation involves making assumptions about, among other things, discount rates, expected rates of return on assets, future salary increases and mortality rates. Due to the long-term nature of these plans, such estimates are subject to significant uncertainty.

NOTE 3: - SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS USED IN THE PREPARATION OF THE FINANCIAL STATEMENTS (CONT.)

- Legal claims

  In estimating the likelihood of outcome of legal claims filed against the Company, the Company relies on the opinion of its legal counsel. These estimates are based on the legal counsel's best professional judgment, taking into account the stage of proceedings and historical legal precedents in respect of the different issues. Since the outcome of the claims will be determined in courts, the results could differ from these estimates.

- Discount rate for a lease liability

  When the Company is unable to readily determine the discount rate implicit in a lease in order to measure the lease liability, the Company uses an incremental borrowing rate. That rate represents the rate of interest that the Company would have to pay to borrow over a similar term and with similar security, the funds necessary to obtain an asset of similar value to the right-of-use asset in a similar economic environment. When there are no financing transactions that can serve as a basis, the Company determines the incremental borrowing rate based on its credit risk, the lease term and other economic variables deriving from the lease contract's conditions and restrictions. In certain situations, the Company is assisted by an external valuation expert in determining the incremental borrowing rate.

- Impairment of goodwill

  The Company reviews goodwill for impairment at least once a year. This requires management to make an estimate of the projected future cash flows from the continuing use of the CGU (or a group of CGUs) to which the goodwill is allocated and to choose a suitable discount rate for those cash flows.

- Determination of Useful Life

  Intangible assets and property, plant and equipment are measured on initial recognition at cost including directly attributable costs. Intangible assets acquired in a business combination are measured at fair value at the acquisition date. In determining the useful life and the depreciation or amortization method, the Company assesses the period over which an asset is expected to be available for use by the Company and the pattern in which the asset's future economic benefits are expected to be consumed by the Company.

- Purchase price allocation

  The Company allocates the purchase price based on the identifiable assets acquired and liabilities assumed at the acquisition date. The assets and the liabilities assumed are measured at fair value on the acquisition day. Significant estimates are required to measure the fair value of the assets and liabilities recognized as a result of the business combination including future cash flows, discount rate, volatility rate.

- Determining the fair value of an unquoted financial asset or liability

  The fair value of unquoted financial assets or liability in Level 3 of the fair value hierarchy is determined using valuation techniques, generally using future cash flows discounted at current rates applicable for items with similar terms and risk characteristics. Changes in estimated future cash flows and estimated discount rates, after consideration of risks such as liquidity risk, credit risk and volatility, are liable to affect the fair value of these assets of liability.

  Contingent consideration is measured at fair value. The fair value is determined using valuation techniques and method, using future cash flows discounted. This requires management to make an estimate of the projected future cash flows. For information regarding contingent consideration, please refer to Note 5 and Note 16.

NOTE 4: NEW ACCOUNTING STANDARDS OR AMENDMENTS FOR 2023 AND FORTHCOMING REQUIREMENTS

a. New Currently Effective Requirements

- **Amendment to IAS 1, *Presentation of Financial Statements: "Disclosure of Accounting Policies."***

  According to the amendment to IAS 1, companies must provide disclosure of their material accounting policies rather than their significant accounting policies. Pursuant to the amendment, accounting policy information is material if, when considered with other information disclosed in the financial statements, it can be reasonably be expected to influence decisions that the users of the financial statements make on the basis of those financial statements.

  The amendment to IAS 1 also clarifies that accounting policy information is expected to be material if, without it, the users of the financial statements would be unable to understand other material information in the financial statements. The amendment also clarifies that immaterial accounting policy information need not be disclosed.

  The Company adopted *Disclosure of Accounting Policies* from January 1, 2023. Although the amendment did not result in any changes to the accounting policies themselves, it impacted the accounting policy information disclosed in the financial statements.

  See Note 2: Material accounting policies.

- **Amendment to IAS 12, Income Taxes: Deferred Tax related to Assets and Liabilities arising from a Single Transaction**

  The amendment narrows the scope of the exemption from recognizing deferred taxes as a result of temporary differences created at the initial recognition of assets and/or liabilities, so that it does not apply to transactions that give rise to equal and offsetting temporary differences.

  As a result, companies will need to recognize a deferred tax asset or a deferred tax liability for these temporary differences at the initial recognition of transactions that give rise to equal and offsetting temporary differences, such as lease transactions and provisions for decommissioning and restoration.

  The amendment is effective for annual periods beginning on January 1, 2023.

  The amendment did not have a material impact on the Company's financial statements refer to note 22 for additional information.

b. Forthcoming requirements

- **Amendment to IAS 1, *Presentation of Financial Statements: Classification of Liabilities as Current or Non-Current* and subsequent amendment: *Non-Current Liabilities with Covenants***

  The amendment, together with the subsequent amendment to IAS 1 (see hereunder) replaces certain requirements for classifying liabilities as current or non-current. According to the amendment, a liability will be classified as non-current when the entity has the right to defer settlement for at least 12 months after the reporting period, and it "has substance" and is in existence at the end of the reporting period. According to the subsequent amendment, as published in October 2022, covenants with which the entity must comply after the reporting date do not affect classification of the liability as current or non-current. Additionally, the subsequent amendment adds disclosure requirements for liabilities subject to covenants within 12 months after the reporting date, such as disclosure regarding the nature of the covenants, the date they need to be complied with and facts and circumstances that indicate the entity may have difficulty complying with the covenants. Furthermore, the amendment clarifies that the conversion option of a liability will affect its classification as current or non-current, other than when the conversion option is recognized as equity.

  The amendment and subsequent amendment are effective for reporting periods beginning on or after January 1, 2024, with earlier application being permitted. The amendment and subsequent amendment are applicable retrospectively, including an amendment to comparative data.

  The Company does not expect the Amendment to have a material adverse impact on its financial statement.

NOTE 5: - BUSINESS COMBINATIONS

a. Acquisition of an FDA-Licensed Plasma Collection Center

On March 1, 2021, the Company entered into an Asset Purchase Agreement with the privately held B&PR of Beaumont, TX, USA, for the acquisition of the FDA registered plasma collection facility as well as certain related rights and assets. The plasma collection facility currently specializes in the collection of hyper-immune plasma used in the manufacturing of KAMRHO (D), KAMRAB and KEDRAB. The acquisition, for a total consideration of $1,614 thousand, was consummated through the Company's wholly owned subsidiary Kamada Plasma LLC, which operates the Company's plasma collection activity in the U.S.

The Company accounted for the acquisition as a business combination.

The following table details the acquisition consideration:

	USD in thousands
Cash paid	$ 1,404
Payables for acquisition(a)	210
Total acquisition cost	1,614

(a) The acquisition consideration totaled $1,654 thousand, of which an amount of $1,404 thousand was paid at closing, and the balance of $250 thousand was paid in March 2022. The fair value of such deferred consideration was estimated at $210 as of the date of acquisition.

In connection with the acquisition, the Company incurred costs of $140 thousand which included legal and other consulting fees. These costs were recorded in general and administrative expenses in the statement of profit and loss during 2020 and the first quarter of 2021.

The fair value of the identifiable assets and liabilities on the acquisition date:

	USD in thousands
Inventories	184
Property, plant and equipment	82
Intangible assets (a)	962
	1,228
Other current liability	(30)
Net identifiable assets	1,198
Goodwill arising on acquisition (b)	416
Total acquisition cost	1,614

(a) The intangible assets represent the value of the FDA license for the plasma collection facility at fair value (Level 3) at the acquisition date, based on the Greenfield Method. Under such method, the subject intangible asset is valued using a hypothetical cashflow scenario of developing an operating business in an entity that at inception only holds the subject intangible asset. In measuring the FDA license for the plasma collection facility, the Company used an appropriate discount rate of 19%.

(b) The goodwill arising as part of the acquisition is attributed to the expected benefits from the synergies of the combination of the Company's activities and those of the acquired plasma collection facility.

NOTE 5: - BUSINESS COMBINATIONS (CONT.)

b. Acquisition of the Four FDA-Approved Plasma Derived Hyperimmune Commercial Products

On November 22, 2021 (the "Acquisition Date"), the Company entered into the Saol APA for the acquisition of the Four FDA-Approved Plasma Derived Hyperimmune Commercial Products. The acquisition of this portfolio furthered the Company's core objective to become a fully integrated specialty plasma company with strong commercial capabilities in the U.S. market, as well as to expand to new markets, mainly in the Middle East/North Africa region, and to broaden the Company's portfolio offering in existing markets. The four acquired products include:

- CYTOGAM (Cytomegalovirus Immune Globulin Intravenous [Human]) (CMV-IGIV) is a product indicated for the prophylaxis of cytomegalovirus disease associated with the transplantation of the kidney, lung, liver, pancreas, and heart. The product is the sole FDA approved IgG product for this indication.

- VARIZIG [Varicella Zoster Immune Globulin (Human)] is a product that contains antibodies specific for the Varicella zoster virus, and it is indicated for post-exposure prophylaxis of varicella (chickenpox) in high-risk patient groups, including immunocompromised children, newborns, and pregnant women. VARIZIG is intended to reduce the severity of chickenpox infections in these patients. The U.S. Centers for Disease Control (CDC) recommends Varicella zoster immune globulin (human) (such as VARIZIG) for postexposure prophylaxis of varicella for persons at high-risk for severe disease who lack evidence of immunity to varicella. The product is the sole FDA approved IgG product for this indication.

- WINRHO SDF is a Rho(D) Immune Globulin Intravenous (Human) product indicated for use in clinical situations requiring an increase in platelet count to prevent excessive hemorrhage in the treatment of non-splenectomies, for Rho(D)-positive children with chronic or acute immune thrombocytopenia (ITP), adults with chronic ITP, and children and adults with ITP secondary to HIV infection. WinRho SDF is also used for suppression of Rhesus (Rh) Isoimmunization during pregnancy and other obstetric conditions in non-sensitized, Rho(D)-negative women. The product is FDA approved.

- HEPAGAM B is a hepatitis B Immune Globulin (Human) (HBIg) product indicated to both prevent hepatitis B virus (HBV) recurrence following liver transplantation in hepatitis B surface antigen positive (HBsAg- positive) patients and provide post-exposure prophylaxis. The product is FDA approved.

The Company accounted for the acquisition as a business combination.

The following table details the total acquisition consideration as of the Acquisition Date:

	USD in thousands
Cash paid at closing	$ 95,000
Contingent consideration liability (a)	21,705
Deferred consideration (b)	13,788
Settlement of preexisting relationship (c)	(3,786)
Total acquisition cost	126,707

(a) Pursuant to the Saol APA, and in addition to the cash paid at closing, the Company agreed to pay up to $50,000 thousand of contingent consideration subject the achievement of sales thresholds for the period commencing on the Acquisition Date and ending on December 31, 2034. The Company may be entitled for up to $3,000 thousand credit deductible from the contingent consideration payments due for the years 2023 through 2027, subject to certain conditions as defined in the Saol APA. During 2023, the entitlement of the credit was not met. The contingent consideration totaled $21,705 thousand, which represents its fair value (Level 3) at the Acquisition Date, based on an Option Pricing Method (OPM), "Monte Carlo Simulation" model.

In measuring the contingent consideration liability as of the Acquisition Date, the Company used an appropriate risk-adjusted discount rate of 10.6 % and volatility of 13.6%.

NOTE 5: - BUSINESS COMBINATIONS (CONT.)

The fair value of the contingent consideration was $21,855 thousand and $23,534 thousand as of December 31, 2023, and December 31, 2022, respectively. During the year ended December 31, 2023, the Company paid the first sales milestone in the amount of $3,000 thousand, which was accounted for as a reduction of the liability. The Company accounted for $1,321 thousand, $1,539 thousand and $290 thousand, for the years ended December 31, 2023, 2022 and 2021, respectively as financing expenses in the statement of profit and loss to reflects the changes in the fair value of the liability.

In measuring the contingent consideration liability, as of December 31, 2023, and 2022 the Company used an appropriate risk-adjusted discount rate of 11.4% and volatility of 15.17%, and an appropriate risk-adjusted discount rate of 11.8% and volatility of 14.21%, respectively.

As of December 31, 2023, the second sales threshold was met, and the second milestone payment on account of the contingent consideration was paid during February 2024.

For further information about the contingent consideration, refer to Note 14 and Note 16.

(b) Pursuant to the Saol APA, the Company acquired inventory valued at $14,199 thousand which will be paid in ten quarterly installments of $1,500 thousand each or the remaining balance at the final installment. Such deferred inventory consideration totaled $13,788 thousand which represents the Fair value (Level 2) at the Acquisition Date. The interest rate used to calculate such fair value was based on the Company's cost of debt, which was estimated based on the long-term bank loan obtained to partially fund the acquisition. Through December 31, 2023, the Company made eight quarterly installments on account of such inventory related debt. For further information about the deferred consideration, refer to Note 14b and Note 16.

(c) In December 2019, the Company entered into a binding term-sheet for a 12-year contract manufacturing agreement with Saol to manufacture CYTOGAM. Through the Acquisition Date, the Company received a total of $3,786 thousand from Saol to partially fund the technology transfer activities required under such engagement. Such engagement was automatically terminated on the Acquisition Date, and such funds, previously accounted for as deferred revenues, were offset from the acquisition consideration as settlement of preexisting relationship.

The following tables details the fair value of the identifiable assets and liabilities on the Acquisition Date:

	Fair value USD in thousands
Inventory(a)	22,849
Intangible assets(b)	121,174
Assumed liability(c)	(47,213)
Net identifiable assets	98,810
Goodwill arising on acquisition(d)	29,897
Total acquisition cost	126,707

(a) Inventory was valued at cost which represent its fair value.

NOTE 5: - BUSINESS COMBINATIONS (CONT.)

(b) The following table details the intangible assets identified

	Fair value USD in thousands
Customer Relations (1)	33,514
Intellectual property (2)	79,141
Assumed contract manufacturing agreement (3)	8,519
Total Intangible assets	121,174

(1) Customer Relations represents its fair value (Level 3) at the Acquisition Date, based on a Multi Period Excess Earnings Method ("MPEEM"). In measuring the Customer Relations, the Company used an appropriate risk-adjusted discount rate of 11% and churn rate of 5%.

(2) Intellectual property represents its fair value (Level 3) at the Acquisition Date, based on a Relief from Royalties ("RFRM") Method. In measuring the Intellectual property, the Company used an appropriate risk-adjusted discount rate of 11% and Royalties rate of 15.2%.

(3) Assumed contact manufacturing agreement represents its fair value (Level 3) at the Acquisition Date, based on With and Without method. Under the With and Without method the value of an intangible asset is calculated by comparing the cash-flow in a situation where the valued asset is part of the business versus the cash-flow in situation where the asset is not part of the business. The Company used an appropriate risk-adjusted discount rate of 11%.

(c) Pursuant to the Saol APA, the Company assumed certain of Saol's liabilities for the future payment of royalties (some of which are perpetual) and milestone payments to third parties subject to the achievement of corresponding CYTOGAM related net sales thresholds and milestones. The fair value of such assumed liabilities at the Acquisition Date was estimated at $47,213 thousand, which was calculated based on the Option Pricing Method (OPM), Monte Carlo Simulation, and discounted cash flow using a discount rate in the range of 2.25 % and 11% and the volatility of 10.8-14.2%. Refer to Note 14 and Note 16 for more information.

Such assumed liabilities include:

- Royalties:10% of the annual global net sales of CYTOGAM up to $ 25,000 thousand and 5% of net sales that are greater than $ 25,000 thousand, in perpetuity; 2% of the annual global net sales of CYTOGAM in perpetuity; and 8% of the annual global net sales of CYTOGAM for a period of six years following the completion of the technology transfer of the manufacturing of CYTOGAM to the Company, subject to a maximum aggregate of $5,000 thousand per year and the total amount of $30,000 thousand throughout the entire six years period.

- Sales milestones: $1,500 thousand in the event that the annual net sales of CYTOGAM in the United States market exceeds $18,766 thousand during the twelve months period ending June 30, 2022. Such milestone was achieved and paid during 2023; and $1,500 thousand in the event that the annual net sales of CYTOGAM in the United States market exceeds $18,390 thousand during the twelve months period ending June 30, 2023. Such milestone was not achieved and was written off the outstanding liability.

- Milestone: $8,500 thousand upon the receipt of FDA approval for the manufacturing of CYTOGAM at the Company's manufacturing facility. During May 2023, the Company received such FDA approval and paid the milestone of $8,500 thousand.

NOTE 5: - BUSINESS COMBINATIONS (CONT.)

(d) The goodwill arising on acquisition is attributed to the expected benefits from the synergies of the combination of the activities of the Company and the acquired business.

As of the Acquisition Date, the Company recognized the fair value of the assets acquired and liabilities assumed in the business combination according to a provisional measurement. As of December 31, 2022, the valuation of the identifiable assets and liabilities was completed. No adjustments were required to be recorded.

The Company incurred acquisition related cost of $1,094 thousand related mainly to legal and other consulting fees. These costs were recorded in general and administrative expenses in the statement of profit and loss during 2021.

NOTE 6: - CASH AND CASH EQUIVALENTS

	December 31,	
	2023	2022
	U.S. Dollars in thousands	
Cash and deposits for immediate withdrawal	$ 40,630	$ 31,411
Cash equivalents in NIS deposits (1)	15,011	2,847
Total Cash and Cash Equivalents	$ 55,641	$ 34,258

(1) The deposits bear interest of 5.1% per year, as of December 31, 2023, and 2.85%-3.8% per year as of December 31, 2022.

NOTE 7: - TRADE RECEIVABLES, NET

	December 31,	
	2023	2022
	U.S. Dollars in thousands	
Open accounts:		
In NIS	$ 9,084	$ 9,469
In USD	10,642	17,659
	$ 19,726	$ 27,128
Checks receivable	151	124
	$ 19,877	$ 27,252
Less allowance for doubtful accounts(1)	-	-
Total Trade receivables, net	$ 19,877	$ 27,252

(1) As of December 31, 2023 and 2022 no allowance for doubtful accounts was recognized.

NOTE 7: - TRADE RECEIVABLES, NET (CONT.)

An analysis of past due but not impaired trade receivables with reference to reporting date:

	Past due trade receivables with aging of						
	Neither past due nor impaired	Up to 30 Days	31-60 Days	61-90 Days	91-120 Days	Over 121 days	Total
December 31, 2023	$ 18,294	$ 1,391	$ 11	$ 10	$ 26	$ 145	$ 19,877
December 31, 2022	$ 22,710	$ 3,260	$ 788	$ 84	$ 7	$ 402	$ 27,252

NOTE 8: - OTHER ACCOUNTS RECEIVABLES

	December 31,	
	2023	2022
	U.S. Dollars in thousands	
Prepaid expenses	$ 4,405	$ 3,875
Inventory designated for R&D activities	-	3,732
Government authorities	981	645
Derivatives financial instruments mainly measured at fair value through other comprehensive income	149	-
Accrued income	45	451
Other(1)	385	7
Total Other Accounts Receivables	$ 5,965	$ 8,710

(1) The balance includes short-term lease in the amount of $134 thousand that was classified to other accounts receivables (refer to Note 15 for further details), and $247 thousand bank guarantee provided (refer to Note 19 for further details).

NOTE 9: - INVENTORIES

	December 31,	
	2023	2022
	U.S. Dollars in thousands	
Finished products	$ 42,526	$ 30,429
Purchased products	11,021	4,754
Work in progress	6,653	12,276
Raw materials	28,279	21,326
Total Inventories	$ 88,479	$ 68,785

(1) During the years 2023, 2022 and 2021, the Company recognized, as cost of revenues, an impairment for inventories carried at net realizable value totaled of $4,399 thousand, $3,996 thousand, and $2,982 thousand, respectively.

NOTE 10: - PROPERTY, PLANT AND EQUIPMENT

a. Composition and changes:

2023

	Land and Buildings (1)	Machinery and Equipment (1)	Vehicles	Computers, Software, Equipment and Office Furniture	Leasehold Improvements (2)	Total
	U.S. Dollars in thousands					
Cost						
Balance at January 1, 2023	$ 35,090	$ 35,343	$ 31	$ 10,337	$ 1,566	$ 82,367
Additions	951	2,764	-	1,135	1,544	6,394
Sale and write-off	-	(110)	-	-	(17)	(127)
Balance as of December 31, 2023	36,0418	37,997	31	11,472	3,093	88,631
Accumulated Depreciation						
Balance as of January 1, 2023	22,154	25,493	26	7,882	655	56,210
Depreciation	1,140	1,875	3	1,168	123	4,309
Sale and write-off	-	(109)	-	-	-	(109)
Balance as of December 31, 2023	23,294	27,259	29	9,050	778	60,410
Depreciated cost as of December 31, 2023	$ 12,747	$ 10,738	$ 2	$ 2,422	$ 2,315	$ 28,224

(1) Including labor costs charged in 2023 to the cost of facilities, machinery, and equipment in the amount of $1,426 thousand.

(2) Including Right – of use assets depreciation expense in the amount of $20 thousand that was capitalized to the Leasehold Improvements during 2023. Also refer to Note 15.

NOTE 10: - PROPERTY, PLANT AND EQUIPMENT (CONT.)

2022

	Land and Buildings (1)	Machinery and Equipment (1)	Vehicles	Computers, Software, Equipment and Office Furniture	Leasehold Improvements	Total
	U.S. Dollars in thousands					
Cost						
Balance at January 1, 2022	$ 34,543	33,439	31	9,371	1,184	78,568
Additions	547	1,906	-	966	382	3,801
Sale and write-off	-	(2)	-	-	-	(2)
Balance as of December 31, 2022	35,090	35,343	31	10,337	1,566	82,367
Accumulated Depreciation						
Balance as of January 1, 2022	21,091	23,804	23	6,808	535	52,261
Depreciation	1,063	1,691	3	1,074	120	3,951
	-	(2)	-	-	-	(2)
Balance as of December 31, 2022	22,154	25,493	26	7,882	655	56,210
Depreciated cost as of December 31, 2022	$ 12,936	$ 9,850	$ 5	$ 2,455	$ 911	$ 26,157

(1) Including labor costs charged in 2022 to the cost of facilities, machinery, and equipment in the amount of $1,403 thousands.

b. As for liens, refer to Note 19.

c. Leasing rights of land from the Israel land administration.

	December 31,	
	2023	2022
	U.S. Dollars in thousands	
Under finance lease	$ 1,091	$ 1,119

Kamada Assets Ltd., a subsidiary of the Company, capitalized leasing rights from the Israel Lands Administration for an area of 16,880 m² in Beit Kama, Israel, on which the Company's manufacturing plant and other buildings are located. As part of a new outline which were approved during 2021, the plant area was adjusted to 14,880 m². The amount attributed to capitalized rights is presented under property, plant and equipment and is depreciated over the leasing period, which includes the option period. During 2010, Kamada Assets signed an agreement with the Israel Lands Administration to consolidate its leasing rights and extend the lease period to 2058; the lease also includes an extension option allowing the parties to extend the lease for an additional 49 years following the conclusion of the initial term.

NOTE 11: - INTANGIBLE ASSETS, GOODWILL AND OTHER LONG TERM ASSETS

	December 31,	
	2023	2022
	U.S. Dollars in thousands	
Intangible Assets and Goodwill	139,955	147,009
Long term pre-paid expenses	510	63
Total Other Long-Term Assets	$ 140,465	$ 147,072

1. Intangible Assets:

(a) Composition and changes

2023

	Intellectual property	Customer Relationships	Goodwill	Other Intangibles (1)	Total
	U.S. Dollars in thousands				
Cost:					
Balance as of January 1, 2023	80,103	$ 33,514	$ 30,313	$ 11,101	$ 155,031
Purchases	-	-	-	129	129
Balance as of December 31, 2023	$ 80,103	$ 33,514	$ 30,313	$ 11,230	$ 155,160
Accumulated amortization and impairment:					
Balance as of January 1, 2023	5,853	1,855	-	314	8,022
Amortization recognized in the year	5,376	1,676	-	131	7,183
Balance as of December 31, 2023	11,229	3,531	-	444	15,204
Amortized cost at December 31, 2023	$ 68,874	$ 29,983	$ 30,313	$ 10,785	$ 139,955

(1) Includes assumed contract manufacturing agreement and distribution right of certain therapeutic products to be distributed in Israel, subject to IL MOH and or EMA marketing authorization. The Company was required to make certain upfront and milestone payments on account of such distribution rights. These payments are accounted for as long-term assets through obtaining IL MOH marketing authorization and will subsequently be amortized during the expected distribution right's useful life.

2022

	Intellectual property	Customer Relationships	Goodwill	Other Intangibles(1)	Total
	U.S. Dollars in thousands				
Cost:					
Balance as of January 1, 2022	80,103	33,514	30,313	10,501	154,431
Purchases	-	-	-	600	600
Balance as of December 31, 2022	$ 80,103	$ 33,514	$ 30,313	$ 11,101	$ 155,031
Accumulated amortization and impairment:					
Balance as of January 1, 2022	477	179	-	183	839
Amortization recognized in the year	5,376	1,676	-	131	7,183
Balance as of December 31, 2022	5,853	1,855	-	314	8,022
Amortized cost at December 31, 2022	$ 74,250	$ 31,659	$ 30,313	$ 10,787	$ 147,009

NOTE 11: - INTANGIBLE ASSETS, GOODWILL AND OTHER LONG TERM ASSETS (CONT.)

(b) Amortization:

Amortization expenses of intangible assets are classified in statement of profit or loss as follows:

	Year ended December 31,		
	2023	2022	2021
	USD in thousands		
Cost of goods sold	5,376	5,376	574
Selling and marketing expenses	1,807	1,807	265
	7,183	7,183	839

(d) Allocation of goodwill to cash-generating units

	December 31,	
	2023	2022
	U.S. Dollars in thousands	
Proprietary	$ 30,313	$ 30,313

The goodwill is attributed to the Proprietary Products segment, which represent the lowest level within the Company at which goodwill is monitored for internal management purposes.

Impairment test of goodwill for the year ended on December 31, 2023:

Impairment loss for goodwill is recognized if the recoverable amount of the goodwill is less than the carrying amount. The recoverable amount is the greater of fair value less costs of disposal, or value in use of the relevant reporting level (i.e., a CGU of a group of CGUs).

The Company performed an assessment for goodwill impairment for its Proprietary Products segment, which is the level at which goodwill is monitored for internal management purposes, and concluded that the fair value of the Proprietary Products segment exceeds the carrying amount by approximately 16%. The carrying amount of goodwill assigned to this segment is in the amount of $30,313 thousand.

When evaluating the fair value of the Proprietary Products segment, the Company used a discounted cash flow model which utilized Level 3 measures that represent unobservable inputs. Key assumptions used to determine the estimated fair value include: (a) internal cash flows forecasts for 5 years following the assessment date, including expected revenue growth, costs to produce, operating profit margins and estimated capital needs; (b) an estimated terminal value using a terminal year long-term future growth rate of -4.8% determined based on the long-term expected prospects of the reporting unit; and (c) a discount rate (post-tax) of 11.8 % which reflects the weighted-average cost of capital adjusted for the relevant risk associated with the Proprietary Products segment's operations.

Actual results may differ from those assumed in the Company's valuation method. It is reasonably possible that the Company's assumptions described above could change in future periods. If any of these were to vary materially from the Company's plans, it may record impairment of goodwill allocated to this reporting unit in the future. A hypothetical decrease in the growth rate of 1% or an increase of 1% to the discount rate would have reduced the fair value of the Proprietary Products segment reporting unit by approximately $4,800 thousand and $21,000 thousand, respectively. The sensitivity analysis described above does not lead to increase of the recoverable amount over the carrying amount.

Based on the Company's assessment as of December 31, 2023, no goodwill was determined to be impaired.

NOTE 12: - TRADE PAYABLES

	December 31,	
	2023	2022
	U.S. Dollars in thousands	
Open debts mainly in USD	$ 11,167	$ 12,731
Open debts in EUR	7,266	10,629
Open debts in NIS	6,371	9,557
Total Trade Payables	$ 24,804	$ 32,917

NOTE 13: - OTHER ACCOUNTS PAYABLES

a. Composition:

	December 31,	
	2023	2022
	U.S. Dollars in thousands	
Employees and payroll accruals	$ 7,542	$ 6,683
Government grants (b)	177	201
Derivatives financial instruments	-	92
Accrued Expenses and Others	542	609
Total Other Accounts Payables	$ 8,261	$ 7,585

b. Government grants:

Presented in the statement of financial position and Profit or Loss and Other Comprehensive Income:

	December 31,	
	2023	2022
	U.S. Dollars in thousands	
Current Assets	$ 104	$ 3
Current liability	$ 177	$ 201
Royalties paid during the year	$ -	$ -
Expense (income) carried to Research and Development cost	$ 61	$ 29

NOTE 14: - LOANS AND FINANCIAL LIABILITIES

a. Bank Loans

	December 31,	
	2023	2022
	U.S. Dollars in thousands	
Bank loans (1)	-	17,407
Less current maturities of bank loans	-	4,444
Total Long term bank loans	$ -	$ 12,963

1. Bank loan:

On November 15, 2021, the Company secured a $40,000 thousand credit facility from Bank Hapoalim, an Israeli bank. The credit facility comprised of the following:

(1) A $20,000 thousand long-term loan. The loan bore an interest at a rate of SOFR (Secured Overnight Financing Rate) +2.18% and was payable over 54 equal monthly installments commencing June 16, 2022.

On September 19, 2023, the Company repaid in full the outstanding balance of the loan.

(2) A $20,000 thousand short-term revolving credit facility. The credit facility bore an interest at a rate of SOFR +1.75%, or a commitment fee of 0.2% calculated over the unutilized balance of the facility. As of December 31, 2022, the Company did not utilize such facility.

The credit facility was in effect for an initial period of 12 months, and effective as of January 1, 2023, the credit facility was amended such that the $20 million short-term revolving credit facility was reduced to a NIS 35 million (approx. $10 million) credit facility and the credit facility was extended for an additional period of 12 months.

Borrowings under the amended credit facility accrue interest at a rate of PRIME + 0.55 and are repayable no later than 12 months from the date advanced. The Company is required to pay an annual fee of 0.275% for the Bank's credit allocation.

As of December 31, 2023, the Company did not utilize such facility. On January 1, 2024, the credit facility was extended for an additional 12 months.

Pursuant to the loan and credit facility agreement, the Company is required to meet the following financial covenants for the years ending December 31, 2022, and onwards:

(1) The Shareholder's Equity shall at no time be less than 30% of the Total Assets; examined on a quarterly basis;

(2) The Shareholder's Equity shall at no time be less than $120,000 thousand; examined on a quarterly basis;

(3) The ratio between:(a) the short term financial debt less current maturities of long term debt (in as much as such are included therein); and (b) the Working Capital, as such term is defined in the loan agreement, shall at no time exceed 0.8; examined on a quarterly basis; and

(4) The ratio between: (a) the EBITDA as such term is defined in the loan agreement; and (b) the current maturities of long term debt to financial institutions plus out of pocket financial expenses, net, reported in the course of four consecutive quarters immediately preceding the examination date, shall not be less than 1.1 during each of the years 2022 and 2024 and not less than 1.25 in the year 2025 and onwards, examined on an annual basis.

As of December 31, 2023 and 2022, the Company was in compliance with the financial covenants.

See Note 14 regarding pledge information related to the bank loans.

NOTE 14: - LOANS AND FINANCIAL LIABILITIES (CONT.)

b. Financial liabilities originated or assumed through business combinations

	December 31,	
	2023	2022
	U.S. Dollars in thousands	
Contingent consideration (1)	21,855	23,534
Assumed liabilities (2)	46,375	61,016
Less current maturities	(14,996)	(29,708)
Total Long term contingent consideration and assumed liabilities	$ 53,234	54,842

(1) The fair value of the contingent consideration was $21,855 thousand and $23,534 thousand as of December 31, 2023, and December 31, 2022, respectively. During the year ended December 31, 2023, the Company paid the first sales milestone in the amount of $3,000 thousand, which was accounted for as a reduction of the liability. The Company accounted for $1,321 thousand, $1,539 thousand, and $290 thousand, for the years ended December 31, 2023, 2022 and 2021, respectively as financing expenses in the statement of profit and loss to reflects the changes in the fair value of the liability.

Through December 31, 2023, the second sales threshold was met, and the second milestone payment was paid during February 2024. Refer to Note 5b and Note 18 for details on the contingent consideration.

(2) The assumed liabilities are measured at amortized cost. The decrease in the balance of the assumed liabilities reflects the changes in time value and changes in expected payments.

The value of the assumed liabilities was $46,375 thousand and $61,016 thousand as of December 31, 2023, and 2022, respectively. During the years ended December 31, 2023, and 2022, the Company paid a total of $14,300 thousand and $5,626 thousand on account of such assumed liabilities. The Company accounted for $341 thousand of financing income and $4,727 thousand, and $704 thousand of financing expenses for the years ended December 31, 2023, 2022 and 2021, respectively to reflects the changes in the value of the assumed liabilities.

NOTE 15: - LEASES

Leases

The Company has lease agreements with respect to the following items:

1. Office and storage spaces:

   On November 2016, the Company entered into a lease agreement for office space and a laboratory facility in Rehovot, Israel for an initial period of ten years (which includes a three-year extension through November 2026). In March 2023, the lease agreement was amended and the lease period was extended for an additional eight years through January 2032.

   On March 7, 2023, the Company's U.S. subsidiary Kamada Plasma LLC entered into a lease agreement for a 12,000 square feet premises in Uvalde, Houston, Texas to be used as a plasma collection center. The lease is in effect for an initial period of ten years commencing February 2024, and includes an option to extend the lease for two consecutive periods of five years each.

2. Vehicles:

   The Company leases vehicles for the use of certain of its employees. The lease term is mainly for three-year periods from several leasing entities.

3. Office equipment (i.e. printing and photocopying machines):

   The Company leases office equipment (i.e., printing and photocopying machines), each for a five-year period.

Right-of-use assets composition and changes in lease liabilities

	Right-of-use-assets				
	Rented Offices[3]	Vehicles	Computers, Software, Equipment and Office Furniture	Total	Lease Liabilities [1][2]
	U.S Dollars in thousands				
As of January 1, 2023	$ 1,732	$ 829	$ 7	$ 2,568	$ 3,193
Additions to right-of-use assets	5,131	1,415	-	6,546	6,682
Termination lease		(109)	-	(109)	(107)
Depreciation expense	(500)	(738)	(6)	(1,244)	-
Exchange rate differences	-	-	-	-	(96)
Repayment of lease liabilities	-	-	-	-	(850)
As of December 31, 2023	$ 6,363	$ 1,397	$ 1	$ 7,761	$ 8,822

(1) The weighted average incremental borrowing rate used to discount future lease payments in the calculation of the lease liability was in the range of 3.06%–7.11% evaluated based on credit risk, terms of the leases and other economic variables.

(2) The balance does not include current maturities of lease of $134 thousand that were classified to other accounts receivables due to expected lease incentive.

(3) Out of the Depreciation expense $20 thousand was capitalized to the Leasehold Improvements.

During 2023, the Company recognized $367 thousand as interest expenses on lease liabilities.

During 2023, the total cash outflow for leases was $850 thousand.

NOTE 15: - LEASES (CONT.)

	Right-of-use-assets				
	Rented Offices	Vehicles	Computers, Software, Equipment and Office Furniture	Total	Lease Liabilities[1]
	U.S Dollars in thousands				
As of January 1, 2022	$ 2,165	$ 913	$ 15	$ 3,093	$ 4,314
Additions to right -of -use assets	-	551	-	551	551
Lease termination	-	(52)	-	(52)	(59)
Depreciation expense	(433)	(583)	(8)	(1,024)	
Exchange rate differences	-	-	-	-	(448)
Repayment of lease liabilities	-	-	-	-	(1,164)
As of December 31, 2022	$ 1,732	$ 829	$ 7	$ 2,568	$ 3,193

(1) The weighted average incremental borrowing rate used to discount future lease payments in the calculation of the lease liability was in the range of 1.94%-4.6% evaluated based on credit risk, terms of the leases and other economic variables.

During 2022, the Company recognized $148 thousand as interest expenses on lease liabilities.

During 2022, the total cash outflow for leases was $1,164 thousand.

Maturity analysis of the Company's lease liabilities (including interest):

As of December 31, 2023:

	Less than one year	1 to 2	2 to 3	3 to 5	6 and thereafter	Total
Lease liabilities (including interest)	$ 2,918	$ 3,045	$ 1,689	$ 2,009	$ 6,759	$ 16,420

As of December 31, 2022:

	Less than one year	1 to 2	2 to 3	3 to 5	6 and thereafter	Total
Lease liabilities (including interest)	$ 1,119	$ 907	$ 732	$ 683	$ -	$ 3,441

NOTE 15: - LEASES (CONT.)

Lease extension

The Company has leases that include extension options. These options provide flexibility in managing the leased assets and align with the Company's business needs.

The Company exercises judgement in deciding whether it is reasonably certain that the extension options will be exercised.

The lease agreement entered into by Kamada Plasma LLC for the premises in Uvalde, Texas to be used as a plasma collection center is in effect for an initial period of ten years and Kamada Plasma LLC has the option to extend the lease for two consecutive periods of five years each, upon six months prior written notice. The Company has reasonable certainty that the extension option will be exercised in order to avoid a significant adverse impact to its operating activities.

NOTE 16: - FINANCIAL INSTRUMENTS

a. Classification of financial assets and liabilities

The financial assets liabilities in the balance sheet are classified by groups of financial instruments pursuant to IFRS 9:

	December 31,	
	2023	2022
	U.S. Dollars in thousands	
Financial assets		
Financial assets at fair value through profit or loss:		
Foreign exchange forward contracts	8	-
Total Financial assets at fair value through profit or loss	$ 8	$ -
Financial assets at fair value through other comprehensive income:		
Cash flow hedges	141	-
Total Financial assets at fair value through other comprehensive income:	$ 141	$ -
Financial assets at cost:		
Cash and cash equivalent	55,641	34,258
Total Financial assets at cost	$ 55,641	$ 34,258
Total financial assets	$ 55,790	$ 34,258
Financial liabilities		
Financial liabilities at fair value through profit or loss:		
Foreign exchange forward contracts	-	4
Contingent consideration in business combination	21,855	23,534
Total financial liabilities at fair value through profit or loss	$ 21,855	$ 23,538
Financial liabilities at fair value through other comprehensive income:		
Cash flow hedges	-	88
Total financial liabilities at fair value through other comprehensive income	$ -	$ 88
Financial liabilities measured at amortized cost:		
Assumed liabilities through business combination	46,375	61,016
Bank loans	-	17,407
Leases	8,822	3,193
Total financial liabilities measured at amortized cost	$ 55,197	$ 81,616
Total financial and lease liabilities	$ 77,052	$ 105,242

NOTE 16: - FINANCIAL INSTRUMENTS (CONT.)

b. Financial risk factors

The Company's activities expose it to various financial risks, such as market risk (foreign currency risk, interest rate risk and price risk), credit risk and liquidity risk. The Company's investment policy focuses on activities that will preserve the Company's capital. The Company utilizes derivatives to hedge certain exposures to risk.

Risk management is the responsibility of the Company's management and specifically that of the Company's Chief Executive Officer (CEO) and Chief Financial Officer (CFO), in accordance with the policy approved by the Board of Directors. The Board of Directors provides principles for the overall risk management.

1. Market risks

Foreign exchange risk

The Company operates in an international environment and is exposed to foreign exchange risk resulting from the exposure to different currencies, mainly the NIS and EUR. Foreign exchange risks arise from recognized assets and liabilities denominated in a foreign currency other than the functional currency, such as trade and other accounts receivables, trade and other accounts payables, loans and capital leases.

As of December 31, 2023, and 2022, the Company held financial derivatives intended to hedge changes in the exchange rate of the USD vs. the NIS and the EUR (see also Note 16f. below).

2. Credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents, short-term bank deposits, trade receivables and foreign currency derivative contracts.

a) Cash, cash equivalent and short term investments:

The Company holds cash, cash equivalents, short term deposits and other financial instruments at major financial institutions in Israel and the United States. In accordance with Company policy, evaluations of the relative strength of credit of the various financial institutions are made on an ongoing basis.

Short-term investments include short-term deposits with low risk for a period less than one year.

b) Trade receivables:

The Company regularly monitors the credit extended to its customers and their general financial condition, and, when necessary, requires collateral as security for the debt such as letters of creditor and down payments. In addition, the Company partially insures its overseas sales with foreign trade risk insurance. Refer to Note 7 for additional information.

NOTE 16: - FINANCIAL INSTRUMENTS (CONT.)

The Company keeps constant track of customer debt, and, to the extent required, accounts for an allowance for doubtful accounts that adequately reflects, in the Company's assessment, the loss embodied in the debts the collection of which is in doubt.

The Company's maximum exposure to credit risk for the components of the statement of financial position as of December 31, 2023, and 2022 is the carrying amount of trade receivables.

c) Foreign currency derivative contracts:

The Company is exposed to foreign currency exchange fluctuations, primarily in USD vs. NIS and EUR. Consequently, it enters into various foreign currency exchange contracts with major financial institutions (see also Note 16f. below).

d) Interest rate risk:

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The Company's exposure to the risk of changes in market interest rates relates primarily to the Company's long-term liabilities with floating interest.

3. Liquidity risk

The table below summarizes the maturity profile of the Company's financial liabilities based on contractual undiscounted payments:

December 31, 2023

	Less than one year	1 to 2	2 to 3	3 to 5	6 and thereafter	Total
Trade payables	$ 24,804	-	-	-	-	24,804
Assumed liabilities (1)	11,996	4,152	4,261	7,836	18,130	46,375
Other accounts payables	8,261	-	-	-	-	8,261
Lease liabilities (including interest)	2,918	3,045	1,689	2,009	6,759	16,420
	$ 47,979	7,197	5,950	9,845	24,889	95,860

(1) Due the nature of the account which include infinite payments for royalties and milestones to third parties the assumed liabilities reflect the discounted amount. see Note 18e

NOTE 16: - FINANCIAL INSTRUMENTS (CONT.)

December 31, 2022

	Less than one year	1 to 2	2 to 3	3 to 5	6 and thereafter	Total
Trade payables	$ 32,917	-	-	-	-	$ 32,917
Assumed liabilities	23,708	5,030	4,087	7,928	20,263	61,016
Other accounts payables	7,585	-	-	-	-	7,585
Bank loans (including interest)	4,841	4,677	4,580	4,111	-	18,208
Lease liabilities (including interest)	1,119	907	732	683	-	3,441
	$ 70,170	$ 10,614	$ 9,399	$ 12,722	$ 20,263	$ 123,167

Changes in liabilities arising from financing activities

	January 1, 2023	Payments	Foreign exchange fluctuation	New loans and leases	Business combination	Revaluation	Write off	December 31, 2023
	U.S. Dollars in thousands							
Contingent consideration (1)	23,534	(3,000)	-	-	-	1,321		21,855
Assumed liabilities	61,016	(14,300)		-	-	(341)		46,375
Bank loans	17,407	(17,407)		-	-	-		-
Leases	3,193	(850)	(96)	6,682	-	-	(107)	8,822
Total	$ 105,150	$ (35,557)	$ (96)	$ 6,682	$ -	$ 980	$ (107)	$ 77,052

(1) The contingent consideration fair value as of December 31, 2023, was based on an Option Pricing Method (OPM), "Monte Carlo Simulation" model. In measuring the contingent consideration liability, the Company used an appropriate risk-adjusted discount rate of 11.4% and volatility of 15.17%. totaled $21,855 thousand.

c. Fair value

The following table demonstrates the carrying amount and fair value of the financial assets and liabilities presented in the financial statements not at fair value:

	Carrying Amount December 31,		Fair Value December 31,	
	2023	2022	2023	2022
	U.S. Dollars in thousands			
Assumed liabilities	46,375	61,016	46,468	56,946
Bank loans	-	17,407	-	17,071
Leases	8,822	3,193	8,973	3,183
Total Financial liabilities	$ 55,197	$ 81,616	$ 55,441	$ 77,200

The fair value of the bank loans, leases and the assumed liabilities was based on standard pricing valuation model such as a discounted cash-flow model which considers the present value of future cash flows discounted by an interest rate that reflects market conditions (Level 3).

The carrying amount of cash and cash equivalents, short-term bank deposits, trade and other receivables, trade and other payables approximates their fair value, due to the short-term maturities of the financial instruments.

NOTE 16: - FINANCIAL INSTRUMENTS (CONT.)

d. Classification of financial instruments by fair value hierarchy

Financial assets (liabilities) measured at fair value:

Financial assets (liabilities) measured at fair value:	Level 1	Level 2	Level 3 (1)
	U.S. Dollars in thousands		
December 31, 2023			
Derivatives instruments	-	149	-
Contingent consideration(1)	-	-	(21,855)
	$ -	$ 149	$ (21,855)

Financial assets (liabilities) measured at fair value:	Level 1	Level 2	Level 3 (1)
	U.S. Dollars in thousands		
December 31, 2022			
Derivatives instruments	-	(92)	-
Contingent consideration(1)	-	-	(23,534)
	$ -	$ (92)	$ (23,534)

(1) For changes in Contingent Consideration see above

During 2023 and 2022, there was no transfer due to the fair value measurement of any financial instrument from Level 1 to Level 2, and furthermore, there were no transfers to or from Level 3 due to the fair value measurement of any financial instrument.

Sensitivity tests and principal work assumptions

The selected changes in the relevant risk variables were determined based on management's estimate as to reasonable possible changes in these risk variables.

The Company has performed sensitivity tests of principal market risk factors that are liable to affect its reported operating results or financial position. The sensitivity tests present the profit or loss in respect of each financial instrument for the relevant risk variable chosen for that instrument as of each reporting date. The test of risk factors was determined based on the materiality of the exposure of the operating results or financial condition of each risk with reference to the functional currency and assuming that all the other variables are constant.

	December 31,	
	2023	2022
	U.S. Dollars in thousands	
Sensitivity test to changes in interest rate risk		
Gain (loss) from change:		
1% increase in basis points of SOFR	$ -	$ (13)
1% decrease in basis points of SOFR	$ -	$ 13
Sensitivity test to changes in foreign currency:		
Gain (loss) from change:		
5% increase in NIS	$ (454)	$ (57)
5% decrease in NIS	$ 454	$ 57
5% increase in Euro	$ (271)	$ (389)
5% decrease in Euro	$ 271	$ 389

NOTE 16: - FINANCIAL INSTRUMENTS (CONT.)

e. Linkage terms of financial liabilities by groups of financial instruments pursuant to IFRS 9:

	December 31,	
	2023	2022
	U.S. Dollars in thousands	
In NIS:		
Bank loans measured at amortized cost	$ -	$ -
Leases measured at amortized cost	6,275	3,193
	$ 6,275	$ 3,193
In USD:		
Contingent consideration at fair value through profit or loss	21,855	23,534
Assumed liabilities measured at amortized cost	46,375	61,016
Bank loans measured at amortized cost	-	17,407
Leases measured at amortized cost (1)	2,547	-
	$ 70,777	$ 101,957

1 The balance does not include current maturities of lease of $134 thousand that was classified to other accounts receivables due to expected lease incentive.

f. Derivatives and hedging:

Derivatives instruments not designated as hedging

The Company has foreign currency forward contracts designed to protect it from exposure to fluctuations in exchange rates, mainly of NIS and EUR, in respect of its trade receivables, trade payables. Foreign currency forward contracts are not designated as cash flow hedges, fair value or net investment in a foreign operation. These derivatives are not considered as hedge accounting. As of December 31, 2023, the fair value of the derivative instruments not designated as hedging was a financial asset of $8 thousand. The open transactions for those derivatives were in an amount of $9,149 thousands.

Cash flow hedges:

As of December 31, 2022, the Company held NIS/USD hedging contracts (cylinder contracts) designated as hedges of expected future salaries expenses and for expected future purchases from Israeli suppliers.

The main terms of these positions were set to match the terms of the hedged items. As of December 31, 2023, the fair value of the derivative instruments designated as hedge accounting was an asset of $141 thousand. The open transactions for those derivatives were in an amount of $389 thousand.

Cash flow hedges of the expected salaries and suppliers' expenses as of December 31, 2023, were estimated as effective and accordingly a net unrecognized income was recorded in other comprehensive income in the amount of $228 thousand, net. The ineffective portion was allocated to finance expenses.

NOTE 17: - EMPLOYEE BENEFIT LIABILITIES, NET

Employee benefits consist of short-term benefits and post-employment benefits.

Post-employment benefits:

According to the labor laws and Israeli Severance Pay Law, the Company is required to pay compensation to an employee upon dismissal or retirement or to make current contributions in defined contribution plans pursuant to Section 14 of the Israeli Severance Pay Law, as specified below. The Company's liability is accounted for as a post-employment benefit only for employees not under Section 14. The computation of the Company's employee benefit liability is made in accordance with a valid employment contract, or a collective bargaining agreement based on the employee's salary and employment terms which establish the entitlement to receive the compensation.

The post-employment employee benefits are normally financed by contributions classified as defined benefit plans, as detailed below:

1. Defined contribution deposit:

   Israeli employees defined contribution plan:

   The Company's agreements with part of its employees are in accordance with Section 14 of the Israeli Severance Pay Law. Contributions made by the Company in accordance with Section 14 release the Company from any future severance liabilities in respect of those employees. The expenses for the defined benefit deposit in 2023, 2022 and 2021 were $925 thousand, $873 thousand, and $1,023 thousand, respectively.

   U.S. employees defined contribution plan:

   Since August 2022, the Company's U.S. subsidiary has a 401(k) defined contribution plan covering certain employees in the U.S. During the years ended December 31, 2023, and December 31, 2022 the U.S. subsidiary recorded expenses for matching contributions in the amount of $62 thousand and $11 thousand, respectively.

2. Defined benefit plans:

   The Company accounts for the payment of compensation as a defined benefit plan for which an employee benefit liability is recognized and for which the Company deposits amounts in a long-term employee benefit fund and in qualifying insurance policies.

3. Expenses recognized in comprehensive income (loss):

	Year Ended December 31,		
	2023	2022	2021
	U.S. Dollars in thousands		
Current service cost	$ 194	$ 223	$ 281
Past service cost	-	-	415
Interest expenses, net	28	15	23
Total employee benefit expenses	222	238	716
Actual return on plan assets	$ 50	$ (25)	$ 349

NOTE 17: - EMPLOYEE BENEFIT LIABILITIES, NET (CONT.)

The expenses are presented in the Statement of Comprehensive income (loss) as follows

	Year Ended December 31,		
	2023	2022	2021
	U.S. Dollars in thousands		
Cost of revenues	$ 155	$ 166	$ 499
Research and development	22	24	90
Selling and marketing	33	27	62
General and administrative	23	21	65
	$ 233	$ 238	$ 716

4. The plan liabilities, net:

	December 31,	
	2023	2022
	U.S. Dollars in thousands	
Defined benefit obligation	$ 4,399	$ 4,379
Fair value of plan assets	3,778	3,707
Total liabilities, net	$ 621	$ 672

5. Changes in the present value of defined benefit obligation

	2023	2022
	U.S. Dollars in thousands	
Balance at January 1,	$ 4,380	$ 5,434
Interest costs	200	78
Current service cost	194	223
Past service cost	-	-
Benefits paid	(376)	(202)
Demographic assumptions	13	(9)
Financial assumptions	(91)	(715)
Past Experience	209	206
Currency Exchange	(130)	(636)
Balance at December 31,	$ 4,399	$ 4,379

6. Plan assets

a) Plan assets

Plan assets comprise assets held by long-term employee benefit funds and qualifying insurance policies.

NOTE 17: - EMPLOYEE BENEFIT LIABILITIES, NET (CONT.)

b) Changes in the fair value of plan assets

	2023	2022
	U.S. Dollars in thousands	
Balance at January 1,	$ 3,707	$ 4,154
Expected return	172	62
Contributions by employer	173	181
Benefits paid	(206)	(181)
Demographic assumptions	-	-
Financial assumptions	-	(4)
Past Experience	50	(20)
Currency exchange	(118)	(485)
Balance at December 31,	$ 3,778	$ 3,707

7. The principal assumptions underlying the defined benefit plan

	2023	2022	2021
		%	
Discount rate of the plan liability	5.3	5.1	3.1
Future salary increases	3.0	3.0	3.0

The sensitivity analyses below have been determined based on reasonably possible changes of the principal assumptions underlying the defined benefit plan as mentioned above, occurring at the end of the reporting period.

In the event that the discount rate would be one percent higher or lower, and all other assumptions were held constant, the defined benefit obligation would decrease by $92 thousand or increase by $124 thousand, respectively.

In the event that the expected salary growth would increase or decrease by one percent, and all other assumptions were held constant, the defined benefit obligation would increase by $118 thousand or decrease by $87 thousand, respectively.

NOTE 18: - CONTINGENT LIABILITIES AND COMMITMENTS

a. On August 23, 2010, the Company entered into a 30 year collaboration agreement with Baxter Healthcare Corporation ("Baxter") with respect for granting of the distribution rights for GLASSIA. During 2015, Baxter assigned all its rights under the collaboration agreement to Baxalta US Inc. ("Baxalta") which was acquired during 2016 by Shire plc. ("Shire"), which is now part of Takeda ("Takeda" and in these consolidated financial statements Baxter, Baxalta and Shire will be referred to as "Takeda").

The collaboration agreement consists of three main agreements (1) an Exclusive Manufacturing, Supply and Distribution agreement for GLASSIA in the United States, Canada, Australia and New Zealand (the "Territory" and the "Distribution Agreement", respectively); (2) Technology License Agreement for the use of the Company's knowhow and patents for the production, continued development and sale of GLASSIA by Takeda (the "License Agreement") in the Territory; and (3) A Paste Supply Agreement for the supply by Takeda of plasma derived fraction IV-1 to be used by the Company for the production of GLASSIA (the "Raw Materials Supply Agreement").

Pursuant to the agreements, the Company was entitled to certain upfront and milestone payments at a total amount of $45 million, and for a minimum commitment of Takeda to acquire GLASSIA produced by the Company over the first five years of the term of the Distribution Agreement. In addition, upon initiation of sales of GLASSIA manufactured by Takeda, the Company would be entitled to royalty payments at a rate of 12% on net sales of Glassia through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually (the "Royalty Payments").

Through December 31, 2021, the Company accounted for as income all of the $45 million associated with the upfront and milestone payments from Takeda pursuant to the Distribution and License Agreements as amended.

On March 31, 2021, the Company entered into an amendment to the Technology License Agreement with Takeda with respect to GLASSIA. Pursuant to the amendment the Company undertook to transfer to Takeda the U.S. Biologics License Application (BLA) of the product upon completion of the transition of GLASSIA manufacturing to Takeda, in consideration for a $2 million payment from Takeda. Such amount was paid by Takeda and accounted for as income during the first quarter of 2022.

During 2021 the Company terminated the production and supply of GLASSIA to Takeda and Takeda initiated its own production of GLASSIA for distribution in the Territory. Accordingly, commencing 2022, Takeda initiated royalty payments to the Company as defined above.

For the years ended December 31, 2023, and 2022 the Company accounted for a total of $16.11 million and $12.2 million from sales-based royalty income from Takeda, respectively.

Pursuant to the Distribution Agreement, Takeda is responsible to conduct any required additional clinical studies required to obtain or maintain GLASSIA's marketing authorization in the Territory. Under certain conditions, the Company will be required to participate in the funding of these clinical studies in a total amount not to exceed $10 million.

Pursuant to the Raw Material Supply Agreement Takeda undertook to provide the Company, free of charge, all quantities of plasma derived fraction IV-1 required by the Company for manufacturing GLASSIA to be sold to Takeda for distribution in the Territory. The Company accounts for the fair value of the plasma derived fraction IV-1 used and sold as revenues and charges the same fair value to cost of revenue. In addition, the Company has the right to acquire from Takeda plasma derived fraction IV-1 for its continued development and for the production, sale and distribution of GLASSIA by the Company outside the Territory.

NOTE 18: - CONTINGENT LIABILITIES AND COMMITMENTS (CONT.)

b. In November 2006, the Company entered into an agreement with PARI GmbH ("PARI") in connection with a supply by PARI of a certain medical device required for the development of the Company's Inhaled AAT product. Pursuant to the agreement, the Company was licensed to use developments made by PARI. Furthermore, PARI will provide the Company certain quantities of devices for carrying out clinical trials, free of charge. In the event that the development is successful, and the underlining product obtains required marketing authorization, the Company will pay PARI royalties based on sales of the devices through the later of the device patents expiration period or 15 years from the first commercial sale of the Company's the Inhaled AAT product.

On expiration of the royalty period, the license will become non-exclusive, and the Company shall be entitled to use the rights granted to it pursuant to the agreement without paying royalties or any other compensation. In addition, and according to a mechanism set in the agreement, PARI would be required to pay royalties to the Company of the total net sales of the device exceeding a certain amount, through the later of the device patents expiration period or 15 years from the first commercial sale of the Company's Inhaled AAT product.

In February 2008, the parties executed an amendment to the agreement according to which the exclusive global license granted to the Company was expanded to two additional indications. The royalties' obligations mentioned above, are applicable to all indications.

In addition, the parties entered into a commercialization and supply agreement, which ensures long-term regular supply of the device, including spare parts.

In May 2019, the Company signed a Clinical Study Supply Agreement ("CSSA") with PARI for the supply of the required quantities of controller kits and the web portal associated with PARI's device required for the Company's continued clinical trials with respect to the Inhaled AAT product. The CSSA is a supplement agreement to the commercialization and supply agreement and will expire upon the expiration or termination of such agreement.

c. In July 2011, the Company entered into a strategic collaboration agreement with Kedrion Biopharma Inc. ("Kedrion") for clinical development, marketing, distribution, and sales in the United States of the Company's rabies immune globulin (Human) under the trade name KEDRAB. The product is manufactured and marketed by the Company in other countries under a different trade name KAMRAB. The Company obtained U.S marketing authorization from the FDA for KEDRAB in August 2017, and the commercial launch of the product in the United States was initiated at the beginning of 2018.

In October 2016, the parties entered into an amendment to the agreement pursuant to which the parties agreed to conduct a required post-marketing-commitment clinical study which was initiated in March 2017 and finalized during 2020. The cost of the study was equally shared between the parties.

In April 2020, the Company entered into a binding term sheet with Kedrion for the co-development, manufacturing and distribution of a human plasma-derived Anti-SARS-CoV-2 polyclonal immunoglobulin (IgG) product as a potential treatment for COVID-19 patients. The plasma-derived Anti-SARS-CoV-2 IgG product was developed and manufactured utilizing the Company's proprietary IgG platform technology. Pursuant to the agreed terms, Kedrion provided plasma, collected at its U.S. plasma collection centers, from donors who have recovered from the virus. The Company was responsible for product development, manufacturing, clinical development, with Kedrion's support, and regulatory submissions. The binding term sheet remained in effect until June 30, 2021. No definitive agreement was entered to between the parties, and the Company terminated this product development program.

In December 2023, the Company entered into a binding memorandum of understanding with Kedrion for the amendment and extension of the distribution agreement between the parties. Under the term of the binding memorandum of understanding, during fiscal years 2024 through 2027, Kedrion will purchase annual minimum quantities of KEDRAB, with aggregate revenues to Kamada of approximately $180 million for such four-year period.

NOTE 18: - CONTINGENT LIABILITIES AND COMMITMENTS (CONT.)

d. In July 2019, the Company entered into a 7-year Master Clinical Services Agreement with a third party for the provision of certain clinical research services and other tasks to be performed by such third party, in connection with the Company's Phase III clinical study for its inhaled AAT product.

e. In December 2019, the Company entered into a binding term sheet for a 12-year contract manufacturing agreement with Saol to manufacture CYOTGAM. As a result of the execution and consummation of the Saol APA as detailed below, which included the acquisition of all rights relating to CYTOGAM, the previous engagement with Saol with respect to this product expired. Following the successful execution of the technology transfer from the previous manufacturer and pending all necessary FDA approvals, the Company obtained during May 2023 FDA approval to manufacture CYTOGAM at its facility in Beit Kama, Israel.

As of December 31, 2023, and 2022, the Company recognized an asset related to the costs to fulfill a contract in the net amounts of $8,495 thousand and $7,577 thousand, respectively Refer to Note 2m for further information.

On November 22, 2021, the Company entered into the Saol APA for the acquisition of the Four FDA-Approved Plasma Derived Hyperimmune Commercial Products.

Under the terms of the Saol APA, the Company paid Saol a $95 million upfront payment, and agreed to pay up to an additional $50 million of contingent consideration subject the achievement of sales thresholds for the period commencing on the Acquisition Date and ending on December 31, 2034. The Company may be entitled for up to $3 million credit deductible from the contingent consideration payments due for the years 2023 through 2027, subject to certain conditions as defined in the agreement between the parties.

As of December 31, 2023, the Company had paid the first milestone payment on account of the contingent consideration and the second sales threshold was met. The second milestone payment on account of the contingent consideration was paid during February 2024.

In addition, the Company acquired inventory valued at $14.2 million and agreed to pay the consideration to Saol in ten quarterly installments of $1.5 million each or the remaining balance at the final installment. As of December 31, 2023, the Company paid eight of the quarterly instalments and the remaining two installments will be paid during the first half of 2024.

As part of the acquisition, the Company assumed certain of Saol's liabilities for the future payment of royalties (some of which are perpetual) and milestone payments to third party subject to the achievement of corresponding CYTOGAM related net sales thresholds and milestones. Such assumed liabilities include:

- Royalties: 10 % of the annual global net sales of CYTOGAM up to $25 million and 5 % of net sales that are greater than $25 million, in perpetuity; 2% of the annual global net sales of CYTOGAM in perpetuity; and, 8% of the annual global net sales of CYTOGAM for period of six years following the completion of the technology transfer of the manufacturing of CYTOGAM to the Company, subject to a maximum aggregate of $5 million per year and for total amount of $30 million throughout the entire six years period.

- Sales milestones: $1.5 million in the event that the annual net sales of CYTOGAM in the U.S. market exceeds $18.8 million during the twelve months period ended June 30, 2022, which milestone was met and the milestone payment was paid during 2023; and $1.5 million in the event that the annual net sales of CYTOGAM in the United States market exceeds $18.4 million during the twelve months period ended June 30, 2023, which milestone was not met.

- Milestone: $8.5 million upon the receipt of FDA approval for the manufacturing of CYTOGAM at Company's manufacturing facility in Israel. During May 2023, the Company received such FDA approval and paid the milestone of $8.5 million.

NOTE 18: - CONTINGENT LIABILITIES AND COMMITMENTS (CONT.)

To partially fund the acquisition costs, the Company secured a $40 million financing facility from an Israeli bank which comprised of a $20 million five-year loan and a $20 million short-term revolving credit facility. During September 2023, the Company repaid in full the outstanding balance of the $20 million five-year loan. Refer to Note 14.

f. In December 2019, the Company entered into an agreement with Alvotech ehf. ("Alvotech"), a global biopharmaceutical company, to commercialize Alvotech's portfolio of six biosimilar product candidates in Israel, upon receipt of regulatory approval from the IL MOH. Pursuant to the agreement the Company is obligated to pay Alvotech certain milestone payments, in advance of the launch of the six biosimilar in Israel. In February 2022, the agreement was extended to include two additional biosimilar products.

g. On January 14, 2021, the Company entered into an agreement with undisclosed international pharmaceutical companies to commercialize one of the distribution products, in Israel. Pursuant to the agreement the Company is obligate to pay royalties in the amount of 24% out of the net revenue from the sale of the product in the Israeli market.

h. In May 2022, the Company terminated a distribution agreement with a third-party engaged to distribute the Company's propriety products in Russia and Ukraine (the "Distributor") and a power of attorney granted in connection with such distribution agreement to an affiliate of the Distributor (the "Affiliate"). In July 2022, the Affiliate filed a request for a conciliation hearing with the court in Geneva relying on the terminated power of attorney and seeking damages for the alleged inability to sell the remaining product inventory previously acquired from the Company and compensation for the lost customer base. The conciliation hearing was held on March 17, 2023, and the Affiliate was granted authorization to proceed to file a Statement of Claim before the competent tribunal within three months. On June 13, 2023, the Affiliate filed its Statement of Claim with the tribunal of first instance in Geneva, seeking alleged damages in the total amount of $6.7 million. The Company was officially notified of such filing on November 17, 2023. The Company has filed a motion with the tribunal of first instance challenging its jurisdiction over the Affiliate's claims, submitting that such claims should have been brought before an arbitral tribunal, as contractually agreed between the parties. Until the tribunal of first instance in Geneva rules on the motion, the Affiliate's claims will not be heard. To date, based on the Company's external legal counsel, it is not possible to assess the prospects of the claim against the Company and any potential liabilities and impact on the Company's business.

NOTE 19: - GUARANTEES AND CHARGES

a. The Company provided a bank guarantee in the amount of $354 thousand mainly in favor of the lessor of its leased office facility in Rehovot, Israel, as guarantee for meeting its obligations under the lease agreement.

b. In connection with the Saol APA, the Company secured a debt facility from an Israeli bank (see Note 14) pursuant to which, the Company undertook not to create any first ranking floating charge over all or materially all of its property and assets in favor of any third party unless certain terms, as defined in the loan agreement, have been satisfied.

c. The Company provided a bank guarantee in the amount of $247 thousand as part of the terms and conditions of a tender. In order to obtain the bank guarantee the Company deposited the full amount of the bank guarantee in a collateral account. Refer to Note 8 for further information.

d. The Company provided a security deposit totaling $417 thousand in accordance with the terms and conditions outlined in the lease agreement for the plasma collection center. This deposit serves as a guarantee to ensure the Company's compliance with its obligations under the lease. Accordance with the terms and conditions, within the initial lease period of 10 years, an expected sum of $40 thousand is anticipated to be reimbursed to the Company annually.

NOTE 20: - EQUITY

a. Share capital

	December 31, 2023		December 31, 2022	
	Authorized	Outstanding	Authorized	Outstanding
Ordinary shares of NIS 1 par value	70,000,000	57,479,528	70,000,000	44,832,843

b. Changes in share capital:

Issued and outstanding share capital:

	Number of shares
Balance as of January 1, 2022	44,799,794
Issue of shares	-
Exercise of options into share units	1,421
Vesting of restricted shares units	31,628
Balance as of December 31, 2022	44,832,843
Issue of shares	12,631,579
Exercise of options into shares units	2,662
Vesting of restricted shares units	12,444
Balance as of December 31, 2023	57,479,528

NOTE 20: - EQUITY (CONT.)

c. Rights attached to Shares

Voting rights at the shareholders general meeting, rights to dividend, rights in case of liquidation of the Company and rights to nominate directors.

d. Share options and restricted shares units

During 2023 and 2022, 42,175 and 8,325 share options, respectively, were exercised, on a net exercise basis, into 2,662 and 1,408 ordinary shares of NIS 1 par value each and 12,444 and 31,608 restricted shares units were vested, respectively. The total consideration from such exercise totaled $4 and $9 thousand for 2023 and 2022, respectively.

For additional information regarding options and restricted shares units granted to employees and management in 2023, refer to Note 21 below.

e. Capital management in the Company

The Company's goals in its capital management are to preserve capital ratios that will ensure stability and liquidity to support business activity and create maximum value for shareholders.

f. Issuance of ordinary shares by the Company

On November 21, 2019, FIMI, the leading private equity firm in Israel acquired from third parties 5,240,956 ordinary shares at a price of $6.00, representing ownership of approximately 13% of the Company's then outstanding shares.

On February 10, 2020, the Company consummated a private placement with FIMI, pursuant to which the Company issued 4,166,667 ordinary shares at a price of $6.00 per share, for total gross proceeds of $25 million. Upon closing of the private placement, FIMI's aggregate ownership represented approximately 21% of the Company's then outstanding shares.

On September 7, 2023, the Company consummated a private placement with FIMI, pursuant to which the Company issued 12,631,579 ordinary shares at a price of $4.75 per share (which represented the average closing price of the Company's shares on NASDAQ during the 20 trading days prior to the date of execution of the private placement), for total gross proceeds of $60 million. Following the closing of the private placement, FIMI beneficially owned approximately 38% of the Company's outstanding ordinary shares and became a controlling shareholder of the Company, within the meaning of the Israeli Companies Law, 1999.

Concurrently with the execution of the share purchase agreement, the Company entered into an amended and restated registration rights agreement with FIMI pursuant to which, among other things, the Company undertook to file with the U.S. Securities and Exchange Commission a registration statement registering the resale of all of the ordinary shares held by FIMI, per its request, at any time commencing after the lapse of six months following the closing of the private placement.

Mr. Ishay Davidi, Ms. Lilach Asher-Topilsky and Mr. Uri Botzer, members of the Company's board of directors, are executives of FIMI.

NOTE 21: - SHARE-BASED PAYMENT

On July 24, 2011, the Company's Board of Directors adopted the 2011 Israeli Share Option Plan. In September 2016, the Company's Board of Directors approved an amendment to the plan, to include the issuance of restricted shares units ("RSU") under the plan and renamed it the Israeli Share Award Plan ("2011 Plan"). In August 2021, the Company's Board of Directors approved a 10-year extension of the 2011 Plan, until August 9, 2031, and adopted a few additional amendments to the 2011 Plan, and the 2011 Plan was further amended in October 2022.

Options and RSU's granted under the 2011 Plan, prior to January 2020, generally vest over a four-year period following the date of the grant in 13 installments: 25% on the first anniversary of the grant date and 6.25% at the end of each quarter thereafter. As of 2020, options and RSUs granted under the 2011 Plan generally vest in four equal annual installments of 25% each.

In February 2022, the Company's Board of Directors adopted the U.S. Taxpayer Appendix to the 2011 Plan (the "U.S. Appendix"), which provides for the grant of options and RSU to persons who are subject to U.S. federal income tax. The U.S. Appendix provides for the grant to U.S. employees of options that qualify as incentive stock options ("ISOs") under the U.S. Internal Revenue Code of 1986, as amended. The U.S. Appendix was approved by our shareholders at the annual general meeting held in December 2022.

a. Expense recognized in the financial statements

The share-based compensation expense that was recognized for services received from employees and members of the Company's Board of Directors is presented in the following table:

	For the Year Ended December 31		
	2023	2022	2021
	U.S. Dollar in thousands		
Cost of revenues	$ 249	$ 308	$ 69
Research and development	167	204	79
Selling and marketing	238	254	34
General and administrative	660	372	347
Total share-based compensation	$ 1,314	$ 1,138	$ 529

b. Share options granted:

1. On February 27, 2023, the Company's Board of Directors approved the grant of options to purchase up to 147,000 ordinary shares of the Company under the 2011 Plan and the US Appendix.

The Company granted, out of the above mentioned, to employees and executive officers the following:

Under the Israeli Share Option Plan:

- On February 27, 2023, options to purchase 60,331 ordinary shares of the Company, at an exercise price of NIS 16.53 (USD 4.50) per share. The fair value of the options calculated on the date of grant using the binomial option valuation model was estimated at $108 thousand.

NOTE 21: - SHARE-BASED PAYMENT (CONT.)

- On March 1, 2023, options to purchase 3,333 ordinary shares of the Company, at an exercise price of NIS 16.63 (USD 4.57) per share. The fair value of the options calculated on the date of grant using the binomial option valuation model was estimated on the date of grant at $6 thousand.

- On March 2, 2023, options to purchase 40,000 ordinary shares of the Company, at an exercise price of NIS 16.76 (USD 4.60) per share. The fair value of the options calculated on the date of grant using the binomial option valuation model was estimated on the date of grant at $71 thousand.

- On April 23, 2023, options to purchase 40,000 ordinary shares of the Company, at an exercise price of NIS 17.67 (USD 4.83) per share. The fair value of the options calculated on the date of grant using the binomial option valuation model was estimated on the date of grant at $65 thousand.

Under the US Appendix:

- On February 27, 2023, options to purchase 3,333 ordinary shares of the Company, at an exercise price of USD 4.57 per share. The fair value of the options calculated on the date of grant using the binomial option valuation model was estimated on the date of grant at $6 thousand.

2. On May 28, 2023, options to purchase 90,000 ordinary shares of the Company, under the Israeli Share Option Plan, at an exercise price of NIS 19.46 (USD 5.25) per share. The fair value of the options calculated on the date of grant using the binomial option valuation model was estimated on the date of grant at $217 thousand.

3. On August 15, 2023, options to purchase 20,000 ordinary shares of the Company, at an exercise price of NIS 20.07 (USD 5.33) per share. The fair value of the options calculated on the date of grant using the binomial option valuation model was estimated on the date of grant at $37 thousand.

4. On August 21, 2023, options to purchase up to 54,650 ordinary shares of the Company under the 2011 Plan and the US Appendix.

The Company granted, out of the above mentioned, to employees and executive officers the following:

Under the Israeli Share Option Plan:

- On August 21, 2023, options to purchase 24,050 ordinary shares of the Company, at an exercise price of NIS 21.54 (USD 5.68) per share. The fair value of the options calculated on the date of grant using the binomial option valuation model was estimated at $48 thousand.

NOTE 21: - SHARE-BASED PAYMENT (CONT.)

- On September 26, 2023, options to purchase 9,050 ordinary shares of the Company, at an exercise price of NIS 20.60 (USD 5.39) per share. The fair value of the options calculated on the date of grant using the binomial option valuation model was estimated on the date of grant at $17 thousand.
- On October 4, 2023, options to purchase 2,500 ordinary shares of the Company, at an exercise price of NIS 21.51 (USD 5.39) per share. The fair value of the options calculated on the date of grant using the binomial option valuation model was estimated on the date of grant at $5 thousand.

Under the US Appendix:

- On August 21, 2023, options to purchase 7,500 ordinary shares of the Company, at an exercise price of USD 5.86 per share. The fair value of the options calculated on the date of grant using the binomial option valuation model was estimated on the date of grant at $18 thousand.
- On August 30, 2023, options to purchase 9,050 ordinary shares of the Company, at an exercise price of USD 5.91 per share. The fair value of the options calculated on the date of grant using the binomial option valuation model was estimated on the date of grant at $22 thousand.
- On September 25, 2023, options to purchase the 2,500 ordinary shares of the Company, at an exercise price of USD 5.47 per share. The fair value of the options calculated on the date of grant using the binomial option valuation model was estimated on the date of grant at $6 thousand.

5. On September 7, 2023, options to purchase an aggregate 32,000 ordinary shares of the Company, at an exercise price of NIS 21.63 (USD 5.62) per share, were granted to the Company's newly elected external directors (within the meaning of Israeli law), who were appointed following the closing of the private placement with FIMI. The fair value of the options calculated on the date of grant using the binomial option valuation model was estimated at $45 thousand.
6. On February 29, 2024, the Company's Board of Directors approved the grant of options to purchase up to 27,467 ordinary shares of the Company under the 2011 Plan and the US Appendix.

Under the Israeli Share Option plan:

- 20,800 options to purchase ordinary shares of the Company, at exercise price of NIS 23.91 (USD 6.67) per share. The fair value of the options was estimated on the date of grant at $51 thousands.

Under the Israeli Share Option plan:

- 6,667 options to purchase the ordinary shares of the Company, at an exercise price of USD 6.62 per share. The fair value of the options was estimated on the date of grant was estimated at $17 thousands.

e. Change of Awards during the Year

The following table lists the number of share options, the weighted average exercise prices of share options and changes in share options grants during the year:

	2023		2022		2021	
	Number of Options	Weighted Average Exercise Price In NIS	Number of Options	Weighted Average Exercise Price In NIS	Number of Options	Weighted Average Exercise Price In NIS
Outstanding at beginning of year	3,247,814	19.91	1,504,678	20.38	1,660,958	20.38
Granted	343,647	18.60	2,076,800	19.27	-	-
Exercised	(42,175)	19.04	(8,325)	16.47	(28,672)	16.93
Forfeited	(279,305)	19.57	(325,339)	19.14	(127,608)	20.29
Outstanding at end of year	3,269,981	18.82	3,247,814	19.91	1,504,678	20.65
Exercisable at end of year	1,469,084	19.83	1,049,329	20.38	1,067,363	19.78
The weighted average remaining contractual life for the share options		4.01		4.67		3.33

The range of exercise prices for share options outstanding as of December 31, 2023, and 2022 were NIS 16.53- NIS 29.68. Exercise is by net exercise method.

NOTE 21: - SHARE-BASED PAYMENT (CONT.)

f. The following table lists the number of RSUs and changes in RSUs grants during the year:

	Number of RSs		
	2023	2022	2021
Outstanding at beginning of year	14,705	49,561	104,519
Granted	-	-	-
End of restriction period	(12,444)	(31,608)	(52,538)
Forfeited	(386)	(3,248)	(2,420)
Outstanding at end of year	1,875	14,705	49,561
The weighted average remaining contractual life for the restricted share units	0.25	0.96	3.40

g. Measurement of the fair value of share options:

The Company uses the binomial model when estimating the grant date fair value of equity-settled share options. The measurement was made at the grant date of equity-settled share options since the options were granted to employees and Board of Directors members.

The following table lists the inputs to the binomial model used for the fair value measurement of equity-settled share options for the above plan.

	2023	2022	2021[(1)]
Dividend yield (%)	-	-	-
Expected volatility of the share prices (%)	26-38	23-40	-
Risk-free interest rate (%)	3.76-4.70	0.4-3.55	-
Contractual term of up to (years)	6.5	6.5	-
Exercise multiple	2	2	-
Weighted average share prices (NIS)	16.10-19.46	13.6-18.41	-
Expected average forfeiture rate (%)	0-8.5	0-8.5	-

(1) During the year ended December 31, 2021, no grants of options or RSU were made

Under the US Appendix:

	2023	2022	2021[(1)]
Dividend yield (%)	-	-	-
Expected volatility of the share prices (%)	34-47	27-47	-
Risk-free interest rate (%)	3.76-5.03	0.91-3.54	-
Contractual term of up to (years)	6.5	6.5	-
Exercise multiple	-	-	-
Weighted average share prices (NIS)	4.22-5.55	4.8-5.37	-
Expected average forfeiture rate (%)	5.5-8.5	1.9-8.5	-

NOTE 22: - TAXES ON INCOME

a. Tax laws applicable to the Company

Law for the Encouragement of Industry (Taxes), 1969

The Law for the Encouragement of Industry (Taxes), 1969 (the "Encouragement of Industry Law"), provides several tax benefits for "Industrial Companies." Pursuant to the Encouragement of Industry Law, a company qualifies as an Industrial Company if it is a resident of Israel and at least 90% of its income in any tax year (exclusive of income from certain defense loans) is generated from an "Industrial Enterprise" that it owns. An Industrial Enterprise is defined as an enterprise whose principal activity, in a given tax year, is industrial activity.

An Industrial Company is entitled to certain tax benefits, including: (i) a deduction of the cost of purchases of patents, know -how and certain other intangible property rights (other than goodwill) used for development or promotion of the Industrial Enterprise in equal amounts over a period of eight years, beginning from the year in which such rights were first used, (ii) the right to elect to file consolidated tax returns, under certain conditions, with additional Israeli Industrial Companies under its control, and (iii) the right to deduct expenses related to public offerings in equal amounts over a period of three years beginning from the year of the offering.

Eligibility for benefits under the Encouragement of Industry Law is not contingent upon the approval of any governmental authority. The Company believes that it currently qualifies as an industrial company within the definition of the Industry Encouragement Law. The Company cannot confirm that the Israeli tax authorities will agree that the Company qualifies, or, if qualified, that it will continue to qualify as an industrial company or that the benefits described above will be available to the Company in the future.

Law for the Encouragement of Capital Investments, 1959

Tax benefits prior to Amendment 60

The Company's facilities in Israel have been granted Approved Enterprise status under the Law for the Encouragement of Capital Investments, 1959, commonly referred to as the "Investment Law". The Investment Law provides that capital investments in a production facility (or other eligible assets) may be designated as an Approved Enterprise.

Under the Approved Enterprise programs, a company is eligible for certain benefits such as governmental grants and tax incentives. The benefits period is limited to the earlier of 12 years from completion of the investment or commencement of production ("Year of Operation"), or 14 years from the year in which the certificate of approval was obtained.

The Company's benefit period under the Approved Enterprise programs ended by the end of 2017.

NOTE 22: - TAXES ON INCOME (CONT.)

Tax benefits under Amendment 60

On April 1, 2005, an amendment to the Investment Law was affected ("Amendment 60"). The amendment revised the criteria for investments qualified to receive tax benefits. An eligible investment program under the amendment will qualify for benefits as a Privileged Enterprise (rather than the previous terminology of Approved Enterprise).

The Company received a Tax Ruling from the Israeli Tax Authority that its activity is an industrial activity, and the Company will be eligible for the status of a Privileged Enterprise, provided that it meets the requirements under the ruling. Pursuant to the Tax Ruling, the Year of Election was 2009. The Company also subsequently elected 2012 as a Year of Election. Through December 31, 2023, the Company did not utilize the tax benefits under its Privileged Enterprise and those expired at the end of 2023.

Amendment 68 to the Encouragement Law:

As of January 1, 2011, new legislation amending the Investment Law was affected. Pursuant to Amendment 68 a new status of "Preferred Company" and "Preferred Enterprise", replacing the then existing status of "Privileged Company" and "Privileged Enterprise". A Preferred Company is an industrial company owning a Preferred Enterprise which meets certain conditions (including a minimum threshold of 25% export). However, under this new legislation the requirement for a minimum investment in productive assets was cancelled.

Under Amendment 68, a uniform corporate tax rate will apply to all qualifying income of the Preferred Company, as opposed to the former law, which was limited to income from the Approved Enterprises during the benefits period.

The Company evaluated the effect of the adoption of Amendment 68 on its tax position, and as of the date of the approval of the financial statements, the Company believes that it will not apply for the benefits under Amendment 68.

Amendment 73 to the Encouragement Law:

Amendment 73 to the Encouragement Law also prescribes special tax tracks for technological enterprises, which became effective in 2017, as follows: Preferred technological enterprise, which is defined in the Encouragement Law as a company that owns the enterprise and is a member of a group whose total consolidated revenues are less than NIS 10 billion in the tax year, will be subject to tax at a rate of 12% on profits deriving from intellectual property (in development area A - a tax rate of 7.5%). Special preferred technological enterprise which is a member of a group whose total consolidated revenues exceed NIS 10 billion in the tax year will be subject to tax at a rate of 6% on preferred income from the enterprise, regardless of the enterprise's geographical location. Any dividends distributed to "foreign companies", as defined in the Encouragement Law, deriving from income from the technological enterprises will be subject to tax at a rate of 4%, subject to the conditions prescribed in Section 51Z to the Encouragement Law.

The Company evaluated the effect of the adoption of Amendment 73 on its tax position, and as of the date of the approval of the financial statements, the Company did not apply for the benefits under Amendment 73. The Company may elect to apply for these benefits in the future.

b. Tax rates applicable to the Company (other than the applicable preferred tax)

The Israeli corporate income tax rate was 23% since 2018.

c. Tax assessments

The Company has finalized tax assessments through the end of tax year 2018.

NOTE 22: - TAXES ON INCOME (CONT.)

d. Taxation of the subsidiaries:

Kamada Inc and Kamada Plasma LLC are incorporated in the United States and are subject to U.S. Federal and State tax laws and Franchise Tax. The two subsidiaries file a joint tax return.

On December 22, 2017, the Tax Cuts and Jobs Act (the "Act") was signed into law. Among other things, the Act reduces the corporate tax rate to 21% from 35%.

On February 16, 2022, the Company incorporated KI Biopharma LLC, as a wholly-owned subsidiary of Kamada Ltd. KI Biopharma LLC is a disregarded (tax transparent) entity for U.S. tax purposes.

e. Carry forward losses for tax purposes and other temporary differences

As of December 31, 2023, the Company has carried forward losses and other temporary differences in the amount of $26,929 thousand. Final tax assessments for the years 2019 onwards could have an impact on the balance of carry forward tax losses for which deferred tax asset was not recognized. As of December 31, 2023, the Company did not record deferred tax asset for the remaining carry forward losses due to estimation that their utilization in the foreseeable future is not probable.

f. Uncertain tax positions

The Company analyzed uncertainty involving income taxes on its financial statements and whether it has any potential impact on the financial statements. As of December 31, 2023, and 2022, the application of IFRIC 23 did not have a material effect on the financial statements.

g. Deferred taxes:

The Company records deferred tax assets for carry forward losses and other temporary differences, as their utilization in the foreseeable future is estimated to be probable. As of December 31, 2023, 2022 and 2021 the Company did not record deferred tax assets for the remaining carry forward losses due to estimation that their utilization in the foreseeable future is not probable.

Deferred tax liabilities have not been recognized for the immaterial temporary differences associated with investments in subsidiaries because the disposal of these subsidiaries in the foreseeable future is not probable and because distributions of dividends by these companies are not subject to tax.

h. Taxes on income

	Year ended December 31,		
	2023	2022	2021
	U.S. Dollars in thousands		
Current taxes	$ 145	$ 62	$ 345
Deferred tax expenses (income)	-	-	-
Taxes in respect of prior years	-	-	-
Taxes on income	$ 145	$ 62	$ 345

i. Theoretical tax

2023-2021

The reconciliation between the statutory tax rate and the effective tax rate as recorded in profit or loss for the years ended December 31, 2023, 2022 and 2021 does not provide significant information, mainly because the Company did not recognize deferred taxes, and therefore is not presented.

NOTE 23: - SUPPLEMENTARY INFORMATION TO THE STATEMENTS OF PROFIT AND LOSS

a. Additional information about revenues

	Year Ended December 31,		
	2023	2022	2021
	U.S. Dollars in thousands		
Revenues from major customers each of whom amount to 10% or more, of total revenues			
Customer A[1]	32,800	16,195	11,947
Customer B[2]	$ 16,129	$ 14,205	$ 31,936
Customer C[3]	9,230	12,255	12,357
	$ 58,159	$ 42,655	$ 56,240

(1) Revenue is attributed to the Proprietary segment. Refer to Note 18 (c) for more information.

(2) Revenue is attributed to the Proprietary segment. Refer to Note 18 (a) for more information.

(3) Revenue is attributed mainly to the Distribution segment and in 2023; the total is less than 10% of total Revenues

b. Revenues based on the location of the customers, are as follows:

	Year Ended December 31,		
	2023	2022	2021
	U.S. Dollars in thousands		
U.S.A	$ 73,741	$ 65,296	$ 49,763
Israel	31,296	32,031	35,774
Canada	11,162	10,555	-
Europe	7,088	5,277	5,677
Latin America	12,928	11,293	9,127
Asia	6,147	4,581	3,167
Others	157	306	134
Total Revenue	$ 142,519	$ 129,339	$ 103,642

NOTE 23: - SUPPLEMENTARY INFORMATION TO THE STATEMENTS OF PROFIT AND LOSS (CONT.)

c. Cost of goods sold

	Year Ended December 31,		
	2023	2022	2021
	U.S. Dollars in thousands		
Cost of materials (1)	$ 70,308	$ 53,666	$ 63,945
Salary and related expenses	16,330	14,967	17,486
Subcontractors	6,354	4,673	4,892
Depreciation and amortization (2)	9,000	8,553	3,627
Energy	1,383	1,365	1,464
Other manufacturing expenses	1,235	1,785	1,298
Total Cost of goods sold before Inventory change	100,610	85,009	92,712
Decrease (increase) in inventories	(17,581)	(2,373)	(19,398)
Total Cost of goods sold	$ 87,029	$ 82,636	$ 73,314

(1) Costs of materials for the year ended December 31, 2021, includes $24,282 of inventory obtained in connection with the business combination. Refer to Note 5b for further detail on the business combination.

(2) Including amortization of intangible assets in the amount of $5,376 for each of the years ended December 31, 2023 and 2022, and $574 for the year ended December 31, 2021

d. Research and development

	Year Ended December 31,		
	2023	2022	2021
	U.S. Dollars in thousands		
Salary and related expenses	$ 5,110	$ 5,608	$ 5,076
Subcontractors	4,677	4,216	3,656
Materials and allocation of facility costs	2,971	2,538	1,896
Depreciation and amortization	586	574	616
Others	589	236	113
Total Research and development	$ 13,933	$ 13,172	$ 11,357

For additional information regarding government grant refer to Note 13(b)

e. Selling and marketing

	Year Ended December 31,		
	2023	2022	2021
	U.S. Dollars in thousands		
Salary and related expenses	$ 4,907	4,047	1,930
Packing, shipping and delivery	1,366	1,484	912
Marketing and advertising	2,634	3,676	1,340
Registration and marketing fees	4,362	3,463	1,262
Depreciation and amortization (1)	2,090	2,056	488
Others	834	558	346
Total Selling and marketing	$ 16,193	$ 15,284	$ 6,278

(1) Including amortization of intangible assets in the amount of $1,807 for each of the years ended December 2023 and 2022, and $265 for the year ended December 31, 2021.

NOTE 23: - SUPPLEMENTARY INFORMATION TO THE STATEMENTS OF PROFIT AND LOSS (CONT.)

f. General and administrative

	Year Ended December 31,		
	2023	2022	2021
	U.S. Dollars in thousands		
Salary and related expenses	$ 5,283	$ 4,455	3,853
Employees welfare	1,337	1,299	1,259
Professional fees and public company expense	4,305	4,213	5,055
Depreciation, amortization and impairment	1,035	973	875
Communication and software services	1,201	905	977
Others	1,220	958	617
Total General and administrative	$ 14,381	$ 12,803	$ 12,636

g. Financial (expense) income

	Year Ended December 31,		
	2023	2022	2021
	U.S. Dollars in thousands		
Financial income			
Interest income from cash deposit	$ 588	$ 91	$ 295
Financial expense			
Revaluation of long term liabilities	(980)	(6,266)	(994)
Fees and interest expense to financial institutions	(1,298)	(914)	(283)
Financial income and (expense)			
Derivatives instruments measured at fair value	149	548	(565)
Translation differences of financial assets and liabilities	(94)	(250)	358
Total Financial (expense) income	$ (1,635)	$ (6,791)	$ (1,189)

NOTE 24: - INCOME (LOSS) PER SHARE

a. Details of the number of shares and income (loss) used in the computation of income (loss) per share

	Year Ended December 31,					
	2023		2022		2021	
	Weighted Number of Shares	Income Attributed to equity holders of the Company	Weighted Number of Shares	Income Attributed to equity holders of the Company	Weighted Number of Shares	Income Attributed to equity holders of the Company
		U.S. Dollars in thousands		U.S. Dollars in thousands		U.S. Dollars in thousands
For the computation of basic income (loss)	48,830,479	8,284	44,815,248	$ (2,321)	44,771,766	$ (2,230)
Effect of potential dilutive ordinary shares	4,845,035		41,328	-	130,177	-
For the computation of diluted income (loss)	53,675,514	8,284	44,856,576	$ (2,321)	44,901,943	$ (2,230)

b. The computation of the diluted income per share for the years ending December 31, 2023, 2022 and 2021 considered the options and RSs due to their dilutive effect.

NOTE 25: - OPERATING SEGMENTS

a. General

The operating segments are identified on the basis of information that is reviewed by the chief operating decision makers ("CODM") to make decisions about resources to be allocated and assess its performance. Accordingly, for management purposes, the Company is organized into operating segments based on the products and services of the business units and has two operating segments as follows:

Proprietary Products Development, manufacturing, sales and distribution of plasma-derived protein therapeutics.

Distribution Distribute imported drug products in Israel, which are manufactured by third parties.

Segment performance is evaluated based on revenues and gross profit in the financial statements.

The segment results reported to the CODM include items that are allocated directly to the segments and items that can be allocated on a reasonable basis. Items that were not allocated, mainly the Company's corporate office, research and development costs, sales and marketing costs, general and administrative costs and financial costs (consisting of finance expenses and finance income and including fair value adjustments of financial instruments), are managed on a Company basis.

The segment liabilities do not include loans and financial liabilities as these liabilities are managed on a Company basis. The Company's CODM does not regularly review asset information by segments and, therefore, the Company does not report asset information by segment.

NOTE 25: - OPERATING SEGMENTS (CONT.)

b. Reporting on operating segments

	Proprietary Products	Distribution	Total
	U.S. Dollars in thousands		
Year Ended December 31, 2023			
Revenues	$ 115,458	$ 27,061	$ 142,519
Gross profit	$ 52,116	$ 3,374	$ 55,490
Unallocated corporate expenses			(45,426)
Finance income, net			(1,635)
Income before taxes on income			$ 8,429

	Proprietary Products	Distribution	Total
	U.S Dollars in thousands		
Year Ended December 31, 2022			
Revenues	$ 102,598	$ 26,741	$ 129,339
Gross profit	$ 44,369	$ 2,334	$ 46,703
Unallocated corporate expenses			(42,171)
Finance income, net			(6,791)
Income before taxes on income			$ (2,259)

	Proprietary Products	Distribution	Total
	U.S. Dollars in thousand		
Year Ended December 31, 2021			
Revenues	$ 75,521	$ 28,121	$ 103,642
Gross profit	$ 27,327	$ 3,001	$ 30,328
Unallocated corporate expenses			(31,024)
Finance expense, net			(1,189)
Loss before taxes on income			$ (1,885)

NOTE 26: - BALANCES AND TRANSACTIONS WITH RELATED PARTIES

a. Balances with related parties

	December 31, 2023	December 31, 2022
	U.S. Dollars in thousands	
Trade receivable	$ -	$ 544
Trade payables	$ 96	$ 101
Other accounts payables	$ 45	$ 85

NOTE 26: - BALANCES AND TRANSACTIONS WITH RELATED PARTIES (CONT.)

b. Transactions with employed/directors that accounts as related parties

	Year Ended December 31,		
	2023	2021	2020
	U.S. Dollars in thousands		
Remuneration of directors not employed by the Company or on its behalf	$ 548	$ 331	$ 487
Number of People to whom the Salary and remuneration Refer:			
Directors not employed by the Company	11	9	9
Total Directors employed and not employed by the Company	11	9	9

c. Transactions with key executive personnel (including non-related parties)

	Year Ended December 31,		
	2023	2022	2021
	U.S. Dollars in thousands		
Salary and Related Expenses	$ 3,771	$ 3,590	$ 2,791
Share-based payment	728	547	255
Total	$ 4,499	$ 4,137	$ 3,046

d. Transactions with related parties

	Year Ended December 31,		
	2023	2022	2021
	U.S. Dollars in thousands		
Revenues	$ 2,676	$ 5,298	$ 5,356
Cost of Goods Sold	$ 7	$ 19	$ 51
Selling and marketing expenses	$ -	$ -	$ -
General and administrative expenses	$ 223	$ 214	$ 227

NOTE 26: - BALANCES AND TRANSACTIONS WITH RELATED PARTIES (CONT.)

e. Terms of Transactions with Related Parties

Sales to related parties are conducted at market prices. Outstanding trade receivables due from related parties the end of the year bears no interest and their settlement will be in cash. For the years ended December 31, 2023, 2022 and 2021, the Company recorded no allowance for doubtful accounts for trade receivable due from related parties.

1. Tuteur SACIFIA ("Tuteur"), a company registered in Argentina, was formerly controlled by Mr. Ralf Hahn, the former Chairman of the Company's board of directors, and its currently under the control of the Hahn family. Mr. Ralf Hahn's son, Mr. Jonathan Hahn, currently the President and a director of Tuteur, served as a director of the Company from March 2010 until November 2023.

   In August 2011, the Company entered into a distribution agreement with Tuteur that amended and restated a distribution agreement the parties entered into in November 2001, as amended on August 19, 2014, January 25, 2017, and January 21, 2019, under which Tuteur acted as the exclusive distributor of GLASSIA and KAMRHO(D) in Argentina, Paraguay and Bolivia. The distribution agreement, as amended, expired on December 31, 2019, and pending the execution of a new distribution agreement, the parties continued to act in accordance with the expired distribution agreement.

   In May 2020, the Company entered into a new distribution agreement with Tuteur, which supersedes the former agreement in its entirety, pursuant to which Tuteur serves as the exclusive distributor of GLASSIA and KAMRHO(D) in Argentina, Paraguay, Bolivia and Uruguay. Under the new distribution agreement, Tuteur is responsible, at its own expense, for obtaining marketing authorization and/or registration for each of the products in the foregoing territories that is not already approved and registered. If Tuteur fails to register any product in any territory within 12 months after receipt of our approval of all relevant documents, the Company shall be entitled to terminate the agreement with respect to such product or terminate the exclusivity granted to Tuteur with respect to such product. The agreement includes minimum annual purchase commitments by Tuteur, with respect to sales of any products in territories where registration has been completed, commencing as of the effective date of the agreement, and with respect to sale of any products in the other territories, commencing the first year following the registration of any such product in the applicable territory; and the parties agreed to negotiate in good faith the minimum quantities to be purchased by Tuteur in each following marketing year. If Tuteur fails to purchase and pay for the minimum quantity for any product in any marketing year, the Company is entitled to (i) terminate the agreement on a product-by-product basis and/or (ii) terminate the exclusivity and/or narrow the scope of the territories, if applicable, on a product-by-product basis. The price per product per territory payable by Tuteur pursuant to the agreement will be the higher of 50% of such product's net price sold by Tuteur in the territory or a minimum supply price as defined in the agreement.

   In addition, Tuteur has undertaken to issue a guarantee (from a U.S., Israeli or a western Europe bank) for every new order of product, in the value of each order, which must be provided prior to the shipment of the product and extended through the complete payment of the amount due on any such order or shipment; such guarantee may not be required to the extent we are able to obtain adequate credit insurance covering the value of each order through its complete payment. The Company retain ownership of all relevant intellectual property in the products. The agreement is in effect for a period of five years, and thereafter shall automatically renew for additional periods of one year each, unless either party notifies the other party of its desire to terminate the agreement by prior written notice of at least 12 months before the expiration of any of the additional periods. The Company is entitled to terminate the agreement with respect to all or certain territories in the event of a change of control of Tuteur, its failure to register the products and obtain all marketing approvals within the period set forth above, its failure to purchase and pay for the minimum quantities for two consecutive years (provided that Tuteur will be obligated, during the second marketing year, to purchase the minimum quantity for the preceding marketing year on a product-by-product basis) or if Tuteur discontinues selling the products, after completing registration and obtaining required approvals, for longer than 45 days or 90 days or more in the event such discontinuation is caused due to a force majeure event. The agreement includes a mutual indemnification undertaking, standard confidentiality obligations and obligations of Tuteur to comply with anti-corruption and privacy laws. The agreement includes a non-compete undertaking of Tuteur during the term of the agreement and for a period of 12 months thereunder (other than in the event the agreement is terminated for cause by Tuteur due to the Company's breach of the agreement).

   On July 4, 2022, the Company and Tuteur entered into a supplemental letter agreement to the distribution agreement, pursuant to which Tuteur undertook to be responsible for an investigator-initiated targeted screening program for AATD in Uruguay in patients diagnosed with obtrusive pulmonary disease, with the purpose of identifying patients suitable for treatment with GLASSIA, to be conducted at Sociedad Uruguaya de Neumologia, Montevideo, Uruguay. The Company undertook to support the funding of the study up to $30,000, inclusive of all applicable taxes. Tuteur undertook to provide the Company all collected data, information, results and reports generated or derived as a result of the study, and to obtain in advance all necessary approvals for the study. According to the terms of the agreement, the Company shall not be responsible for or bear any liability arising from or in connection with the study.

NOTE 26: - BALANCES AND TRANSACTIONS WITH RELATED PARTIES (CONT.)

In September 2022, following a decrease in the market price of KAMRHO(D) in Argentina mainly due to the impact of the COVID-19 pandemic and recent changes to treatment protocols that reduced overall consumption of the product, the Company's Board of Directors approved the reduction of the minimum supply price (as defined in the distribution agreement) of the product in Argentina and Paraguay for the 2022 supplies. In February 2023, the Company and Tuteur entered into an amendment to the distribution agreement, pursuant to which KAMRHO(D)'s price for the territories of Argentina and Paraguay payable by Tuteur pursuant to the agreement will be the higher of 60% of KAMRHO(D)'s net price sold by Tuteur in these territories or a minimum supply price (as defined in the amendment to the distribution agreement).

In March 2023, the Company's Board of Directors approved a one-time amendment to the payment terms under the distribution agreement with respect to two shipments of GLASSIA and KAMRHO(D) to be supplied to Tuteur by the end of the first quarter of 2023. In June 2023, due to continued political and economic changes and related mandates imposed by the Argentinian government, the Company's Board of Directors approved further amendments to the distribution agreement, pursuant to which Tuteur may issue a bank guarantee from an Argentinian bank against improved payment terms and supply price.

In January 2024, following additional mandates imposed by the Argentinian government, the Company and Tuteur entered into an amendment to the distribution agreement, pursuant to which, so long as Tuteur does not undergo a "Change of Control" or "Management Change" (as such terms are defined in the amendment), Tuteur will not be required to provide a bank guarantee for orders shipped from December 1, 2023 and onwards, if the total outstanding amount due from Tuteur to the Company does not exceed $1.5 million at any time; provided that such a bank guarantee will be required for any shipment of product that, if shipped, would result in the total outstanding amount due by Tuteur to us to exceed such amount.

2. On July 29, 2015, the Company entered into a distribution agreement with Khairi S.A. ("Khairi"), a company held, inter alia, by Mr. Leon Recanati, which was at the time the Chairman of the Company's Board of Directors, and Mr. Jonathan Hahn, who served as a director of the Company until November 2023, and his siblings, for the distribution of GLASSIA and KAMRHO(D) in Uruguay. The distribution agreement with Khairi was an arm's length transaction. For the years ended on December 31, 2019, 2020 and 2021 there were no sales of product by the Company to Khairi. The agreement expired on December 31, 2020.

3. FIMI, the leading private equity firm in Israel, beneficially owns approximately 38% of the Company's outstanding ordinary shares and is a controlling shareholder of the Company, within the meaning of the Israeli Companies Law, 1999. Refer to Note 20 for further detail.

   The following Israeli entities: G-1 Secure Solutions Ltd., E&M Computing Ltd., and Graffiti Office Supplies & Paper Marketing Ltd., which are controlled by or affiliated with the FIMI Funds, are currently engaged by the Company for the provision of certain services relating to its continuous operations in non-material amounts and at market prices.

f. CEO employment terms

Year	Effective date	Company's Board approval Month/Year	Monthly Gross salary		December 31, 2022	
			NIS		USD	
2020	July 1, 2019	March 2020	₪	88,000	$	25,462
2021	July 1, 2021	October 2021	₪	92,400	$	28,607
2022	July 1, 2022	November 2022	₪	96,000	$	28,575
2023	July 1, 2023	December 2023	₪	100,000	$	27,570

During 2023, the Company accounted for a bonus accrual to the CEO in the amount of $176 thousand.

NOTE 27: - EVENTS SUBSEQUENT TO THE REPORTING PERIOD

With respect to grant of options to employees see Note 21b.

KAMADA LTD.
COMPENSATION RECOUPMENT POLICY

Effective Date: December 1, 2023

In the event of any required accounting restatement of the financial statements of Kamada Ltd. (the "Company") due to the material noncompliance of the Company with any financial reporting requirement under the applicable U.S. federal securities laws or applicable Israeli laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (a "Restatement"), the Board of Directors of the Company (or any committee to which the Board of Directors may delegate its authority) (the "Board") shall recover reasonably promptly from any person, who is or was an executive officer, as such term is defined in Rule 10D-1 adopted under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), of the Company (each, a "Covered Person") the amount of any "Erroneously Awarded Incentive-Based Compensation" (as defined below).

The amount of incentive-based compensation that must be recovered from a Covered Person pursuant to the immediately preceding paragraph in the event that the Company is required to prepare a Restatement is the amount of incentive-based compensation received by a Covered Person that exceeds the amount of incentive-based compensation that otherwise would have been received had it been determined based on the restated amounts and must be computed without regard to any taxes paid (referred to as the "Erroneously Awarded Incentive-Based Compensation"). For incentive-based compensation based on stock price or total shareholder return, where the amount is not subject to mathematical recalculation directly from the information in a Restatement, the amount must be based on a reasonable estimate of the effect of the Restatement on the stock price or total shareholder return, as applicable, upon which the incentive-based compensation was received, and the Company must maintain documentation of that reasonable estimate and provide such documentation to the Nasdaq Stock Market LLC ("Nasdaq"). For the purposes of this policy, incentive-based compensation will be deemed to be received in the fiscal period during which the financial reporting measure specified in the applicable incentive-based compensation award is attained, even if the payment or grant occurs after the end of that period.

In determining the amount of Erroneously Awarded Incentive-Based Compensation to be recovered from a Covered Person, this policy shall apply to all incentive-based compensation received by a Covered Person: (i) after beginning service as an executive officer; (ii) who served as an executive officer at any time during the performance period for the incentive-based compensation; (iii) while the Company has a class of securities listed on a national securities exchange or a national securities association; and (iv) during the three completed fiscal years immediately preceding the date that the Company is required to prepare a Restatement, including any applicable transition period that results from a change in the Company's fiscal year within or immediately following those three completed fiscal years. For this purpose, the Company is deemed to be required to prepare a Restatement on the earlier of: (i) the date the Board, or the Company's officers authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare a Restatement; or (ii) the date a court, regulator, or other legally authorized body directs the Company to prepare a Restatement. The Company's obligation to recover Erroneously Awarded Incentive-Based Compensation is not dependent on if or when the restated financial statements are filed with the Securities and Exchange Commission.

The Company shall recover the Erroneously Awarded Incentive-Based Compensation from Covered Persons unless the Board determines that recovery is impracticable because: (i) the direct expense to a third party to assist in enforcing this policy would exceed the amount of Erroneously Awarded Incentive-Based Compensation; provided that the Company must make a reasonable attempt to recover the Erroneously Awarded Incentive-Based Compensation before concluding that recovery is impracticable, document such reasonable attempt to recover the Erroneously Awarded Incentive-Based Compensation and provide such documentation to Nasdaq; or (ii) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the applicable requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder or any applicable Israeli law.

For purposes of this policy, "incentive-based compensation" refers to any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a "financial reporting measure," which refers to measures that are determined and presented in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standard Board, which are used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures. Stock price and total shareholder return are also financial reporting measures for this purpose. For avoidance of doubt, a financial reporting measure need not be presented within the Company's financial statements or included in a filing with the Securities and Exchange Commission.

In no event will the Company indemnify any Covered Person for any amounts that are recovered under this policy. This policy is in addition to (and not in lieu of) any right of repayment, forfeiture or right of offset against any employees that is required pursuant to any statutory repayment requirement (regardless of whether implemented at any time prior to or following the adoption or amendment of this policy), including Section 304 of the Sarbanes-Oxley Act of 2002. Any amounts paid to the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 shall be considered in determining any amounts recovered under this policy.

The application and enforcement of this policy does not preclude the Company from taking any other action to enforce a Covered Person's obligations to the Company, including termination of employment or institution of legal proceedings. The terms of this policy shall be binding and enforceable against all persons subject to this policy and their beneficiaries, heirs, executors, administrators or other legal representatives.

This policy does not impede any rules applicable to the Company under applicable law, including (without limitation) Israeli law, and is in addition to, and not in lieu of, and shall not derogate from, any other rights or obligations of the Company under applicable law, regulation or rule or any similar policy. This policy shall be interpreted in a manner that is consistent with Rule 10D-1 under the Exchange Act, Rule 5608 of the Nasdaq listing rules and any related rules or regulations adopted by the Securities and Exchange Commission or Nasdaq (the "Applicable Rules") as well as any other applicable law. To the extent applicable law, regulation or rule (including, without limitation, Israeli law or the Applicable Rules) require recovery of incentive-based compensation in additional circumstances besides those specified above, nothing in this policy shall be deemed to limit or restrict the right or obligation of the Company to recover incentive-based compensation to the fullest extent required by applicable law, regulation or rule (including, without limitation, Israeli law or the Applicable Rules) or in any compensation policy, employment agreement, equity plan, equity award agreement or similar arrangement.

-Confidential-

3rd AMENDMENT TO DISTRIBUTION AGREEMENT

This 3rd amendment (the "**Amendment**") to the Distribution Agreement dated May 20, 2020 (the "**Agreement**"), by and between **Kamada Ltd.**, a company organized under the laws of the State of Israel, with its principal office in 2 Holzman Street, Weizmann Science Park, Rehovot 7670402, Israel ("**Supplier**"), and **TUTEUR S.A.C.I.F.I.A.**, with its principal office at Av. Juan de Garay 850, 2nd Floor, "D", 1153 Buenos Aires, Argentina (the "**Distributor**"), is effective as of June 20, 2023 (the "**Effective Date**").

RECITALS

WHEREAS, section 9.5 of the Agreement determines the terms of payment, section 9.6 determines the Distributor's bank guarantee requirements, and Appendix A determines the Transfer Price and the Minimum Supply Price of the Products; and

WHEREAS, the Parties wish to amend the terms of payment under section 9.5 to [*****] days from the AWB date; and

WHEREAS, the Parties wish to amend section 9.6 to waive the requirement from the Distributer of issuing a bank guarantee when the total outstanding amount due from Distributor to Supplier does not exceed USD$ 1,500,000 (one million and five hundred thousand U.S. Dollars) at any time during that period; and

WHEREAS, the Parties wish to amend the Transfer Price of AAT IV 50ml/1 gram in the territory of Argentina and Uruguay as set forth in Appendix A;

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants, terms and conditions set forth herein, Supplier and the Distributor hereby agree to amend the Agreement as follows:

1. Unless otherwise specified, all terms written in capital letters in this Amendment shall have the same meaning as previously defined in the Agreement.

2. Section 9.5 of the Agreement shall be amended as follows:

   Commencing in December 2023, including shipment with reference invoice: [*****], Distributor shall pay Supplier in full for each Invoice in US Dollars within [*****] days from AWB date.

3. Section 9.6 of the Agreement shall be amended as follows:

   3.1. Notwithstanding the terms indicated under Section 9.6 of the Agreement, Supplier agrees to waive Distributor's requirements to issue a bank guarantee as indicated thereunder for any order shipped from December 1, 2023, and onwards, so long as the total outstanding amount due from Distributor to Supplier does not exceed USD 1,500,000 (one million and five hundred thousand U.S. Dollars) (the "Credit Limit") at any time. A bank guarantee will be required to be issued by Distributor, as per the terms of Section 9.6 of the Agreement, for any required shipment of product that, if shipped, would result in the total outstanding amount due by Distributor to Supplier exceed the Credit Limit; for the avoidance of doubt it is clarified that in such events, the bank guarantee would be issued in an amount equal to the total value of the said shipment irrespective of the amount due by Distributor which is in excess over the Credit Limit.

   Example: in an event whereby the outstanding amount due by Distributer to Supplier at given time is USD 1,400,000, and Distributer requested another shipment at a total value of USD 500,000, then the bank guarantee to be issued by Distributer would be at a value of USD 500,000.

   3.2. The terms of Clause 3.1 above shall immediately and automatically expire, and the original terms indicated under Section 9.6 of the Agreement shall apply as is, if the Distributor undergoes any Change of Control or Management Change (as defined below).

   "Management Change" means any significant alteration in the key executive or decision-making positions, or any change that substantially affects the control or direction of the Distributor.

   "Change of Control" means the direct or indirect acquisition by a person or entity of the shares of the Distributer, representing more than fifty (50%) of the voting rights of the Distributer; or the sale or disposal of all or substantially all assets of the Distributer's assets; or a reorganization of the Distributer leading to the transfer of the rights conferred under the Agreement.

4. The Minimum Supply Price and Transfer Price of AAT IV 50ml/1 gram in the territory of Argentina and Uruguay, as set forth in Appendix A shall be amended as follows:

   The Minimum Supply Price of AAT IV 50ml/1 gram for the territory of Argentina and Uruguay, shall be USD$ [*****] per vial.

   The Transfer Price will be equal to the higher of 50% of the Product's Net Price as sold by Distributer in Argentina and Uruguay, or the Minimum Supply Price.

   Notwithstanding anything to the contrary, the Parties agree that the Transfer Price for the single shipment of June 2023, of [*****] of vials of AAT IV 50ml/1 gram, will be equal to the higher of [*****] of the Product's Net Price as sold by Distributer in Argentina, or the Minimum Supply Price.

5. All provisions of the Agreement that are not expressly amended by the terms of this Amendment shall remain in full force and effect without modification.

6. This Amendment may be signed in one or more counterparts, including by signatures transmitted through electronic signature technology, with a reputable and renowned servicer provider, such as DocuSign or Adobe Sign or equivalent software, showing similar measures of security and identification, each of which shall be deemed one and considered the same original and taken together as one and the same document. The Parties agree that the electronic signatures appearing on this Agreement are the same as handwritten signatures for the purposes of validity, enforceability and admissibility.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be executed by their respective, duly authorized, officers, as of the day and year first above written.

KAMADA LTD.	**TUTEUR S.A.C.I.F.I.A**
By: Mr. Amir London, CEO	By: [*****] Title: [*****]
By: Mr. Chaime Orlev, CFO	

Exhibit 8.1

SIGNIFICANT SUBSIDIARIES

Our significant subsidiaries are set forth below, all of which are either 100% owned by us or controlled by us.

Legal Name	Jurisdiction
KI Biopharma LLC	Delaware
Kamada Inc.	Delaware
Kamada Plasma LLC	Delaware (wholly owned by Kamada Inc.)
Kamada Assets (2001) Ltd.	Israel
Kamada Ireland Limited	Ireland

Exhibit 12.1

I, Amir London, certify that:

1. I have reviewed this annual report on Form 20-F of Kamada Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 6, 2024

/s/ Amir London
Amir London
Chief Executive Officer

Exhibit 12.2

I, Chaime Orlev, certify that:

1. I have reviewed this annual report on Form 20-F of Kamada Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 6, 2024

/s/ Chaime Orlev
Chaime Orlev
Chief Financial Officer

Exhibit 13.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Kamada Ltd. (the "Company") on Form 20-F for the period ended December 31, 2023 as filed with the Securities and Exchange Commission (the "Report"), I, Amir London, Chief Executive Officer of the Company, hereby certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 6, 2024

/s/ Amir London
Amir London
Chief Executive Officer

In connection with the Annual Report of Kamada Ltd. (the "Company") on Form 20-F for the period ended December 31, 2023 as filed with the Securities and Exchange Commission (the "Report"), I, Chaime Orlev, Chief Financial Officer of the Company, hereby certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 6, 2024

/s/ Chaime Orlev
Chaime Orlev
Chief Financial Officer

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form F-3 No. 333-274443) of Kamada Ltd, and

(2) Registration Statement (Form S-8 Nos. 333-192720, 333-207933, 333-215983, 333-222891, 333-233267 and 333-265866) pertaining to the 2011 Israeli Share Award Plan of Kamada Ltd;

Of our reports dated March 6, 2024, with respect to the consolidated financial statements of Kamada Ltd. and the effectiveness of internal control over financial reporting of Kamada Ltd. included in this Annual Report (Form 20-F) of Kamada Ltd. for the year ended December 31, 2023.

/s/ KOST FORER GABBAY & KASIERER

KOST FORER GABBAY & KASIERER
A member of EY Global

March 6, 2024
Tel Aviv, Israel